

EPA Jacket 88781-1

Material Sent for Data Extraction

Reg. # 88781-1

Description: _____

☒ Material(s) Sent to Data Extraction Contractors:

☒ New Stamped Label Dated 8/27/12

☐ Notification Dated _____

☒ New CSF(s) Dated 10/17/11

☐ Other: _____

☐ Decision #: _____

☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: S. Hill

Phone: 347-8961 Division: RD

Date: 8/27/12



U.S. ENVIRONMENTAL PROTECTION

Office of Chemical Safety and Pollution Prevention
Office of Pesticide Programs
Registration Division (7504P)
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

EPA Reg.
Number:

88781-1

Date of Issuance:

AUG 27 2012

Term of Issuance:

Unconditional

Name of Pesticide Product:

Willowood
Mepiquat Chloride
Technical

Name and Address of Registrant (include ZIP Code):

Willowood Mepiquat Chlordie, LLC
1600 N.W. Garden Valley Blvd.
Suite 120
Roseburg, OR 97471

Mailed to Agent:

Catherine Byrd
Wagner Regulatory Associates, Inc.
P.O. Box 640
Hockessin, DE 19707

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

Page 1 of 2

Signature of Approving Official:

Maria C. Parker

For Cynthia Giles-Parker, Acting Product Manager 20

Date:

AUG 27 2012


On page 1,

2. Change the product registration number to 88781-1.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. Submit one copy of the revised final printed label for the record before the product is released for shipment.

The basic CSF (dated 10/17/11) is acceptable and will be added to the regulatory file. A copy of the label stamped "Accepted with Comments" is enclosed for your records. If you have any questions, please contact Shaunta Hill at 703-347-8961 or hill.shaunta@epa.gov.

Sincerely,

For 
Cynthia Giles-Parker,
Acting Product Manager 20
Fungicide Branch
Registration Division (7505P)

Enclosure:
Label stamped "Accepted with Comments"
Product Chemistry review
Acute Toxicity review

Willowood Mepiquat Chloride Technical**Active Ingredient:**

Mepiquat Chloride: N, N-dimethylpiperidinium chloride 98.6%

Other Ingredients 1.4%**Total:** 100.0%**KEEP OUT OF REACH OF CHILDREN
WARNING****First Aid**

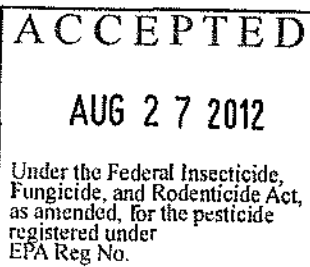
IF SWALLOWED	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 to 20 minutes. • Call a poison control center or doctor for treatment advice.
If INHALED	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
<p>Have the product container or label with you when calling a poison control center, doctor, or going for treatment. For emergency information concerning this product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378 seven days a week, 6:30 am to 4:30 pm Pacific Time (NPIC Web site: www.npic.orst.edu) .</p>	

EPA Reg. No.

EPA Est. No.

Net Contents: _____

Manufactured for:
Willowood Mepiquat Chloride LLC
1600 NW Garden Valley Blvd, Suite 120
Roseburg, OR 97471



88781-1

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING**

May be fatal if swallowed. Harmful if absorbed through skin or inhaled. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Avoid breathing dust. Wash thoroughly with soap and warm water after handling and before eating, drinking, or using tobacco. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only for formulation into a plant growth regulator for use on cotton.

This product may be used to formulate products for any additional use(s) not listed on this label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding support of such use(s).

Each formulator using this product to formulate an end use pesticide product is responsible for obtaining an EPA registration for its end use product.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage: Store in a cool dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food, and feed. Store in original container and out of the reach of children, preferably in a locked storage area.

Pesticide Disposal: Pesticide wastes are toxic. Improper disposal of excess pesticide or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Handling:

Container Handling (Bags): Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Then offer for recycling if available or reconditioning if appropriate or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Container Handling (Plastic): Nonrefillable container. Do not reuse or refill this container. Triple rinse (or equivalent). Then offer for recycling if available or reconditioning if appropriate or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

REFILLABLE CONTAINER: Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into formulation equipment. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Willowood Mepiquat Chloride LLC. To the extent consistent with applicable law, all such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, WILLOWOOD MEPIQUAT CHLORIDE LLC MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. To the extent consistent with applicable law, no agent of Willowood Mepiquat Chloride LLC is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, WILLOWOOD MEPIQUAT CHLORIDE LLC DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT WILLOWOOD MEPIQUAT CHLORIDE LLC'S ELECTION, THE REPLACEMENT OF PRODUCT.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

SUBJECT: Product Chemistry Review of "Willowood Mepiquat Chloride Technical"
TGAI/MUP

DATE: 07/10/12

FROM: Indira Gairola Product Chemistry Team
Technical Review Branch / Registration Division (7505P)

TO: Shaunta Hill/ Shaja Joyner PM 20
Fungicide Branch Registration Division (7505P)

DP BARCODE: 402414

DECISION NO.: 456565

REGISTRATION NO./FILE SYMBOL NO.: 88781-R

PRODUCT NAME: Willowood Mepiquat Chloride Technical

PC CODE: 109101

REGISTRANT: Willowood Mepiquat Chloride, LLC

USE: Fungicide

FOOD USE: Yes ☐ No ☒

MRID NUMBERS: 488213-01

INTRODUCTION:

As per TRB request applicant has submitted additional information regarding the issues raised for the aforementioned subject product. Applicant has submitted MRID # 488213-01 corresponding to guideline 830.1550, 830.1600, 800.1620, 830.1650 & 830.1670. Previously applicant submitted product chemistry data for "Willowood Mepiquat Chloride Technical. In support of the application, the applicant submitted Group A product chemistry data with MRID Nos. 486308-01 and 486308-02, and Group B product chemistry data with MRID No. 486308-03. The CSF for the basic formulation (dated 10/17/12) was submitted for the product. These data were reviewed in March 2012.

For details please refer to review by Indira Gairola dated 03/13/12 under DP bar code 396077.

SUMMARY OF FINDINGS:

1. Group A guidelines:

Following issues were addressed

830.1620 (description of production process)

The submitted data are acceptable (MRID 486308-01). Description of the production process, a flow chart, and quality control measures were provided. Applicant has provided quantities of the starting materials used and the product produced in the manufacturing process. The information presented meets the data requirements for 40 CFR 158.160.

830.1670 (discussion on the formation of impurities)

The submitted data are acceptable. [REDACTED] impurities [REDACTED] were present at levels greater than 0.1% (MRID 486308-01). The origin of the impurity [REDACTED] has been provided (MRID 488213-01).

The information presented meets the data requirements for 40 CFR 158.167.

830.1800 (enforcement analytical method)

The submitted data were not acceptable because the analytical method used for verification of the certified limits for the AI is HPLC-UV and with external standard calibration (MRID 486308-02). The method was not validated for linearity and accuracy. Applicant has stated since the actual recovery is done by spiking known amount of the target analyte to the test solution and determining the amount found and comparing to the added amount, because of this procedure accuracy is not possible since the solution already contains > 98% of active ingredient. Hence the method could not be validated for linearity and accuracy.

Accuracy recovery is applicable only to impurities and formulated products.

TRB will accept the aforementioned reason

The information presented meets the data requirements for 40 CFR 158.180.

CONCLUSIONS:

The TRB has reviewed additional product chemistry data submitted for Technical TGA1 (produced by Willowood Mepiquat Chloride, LLC) and has concluded that:

1. The product chemistry data submitted corresponding to guideline 830.1620 (description of production process) are acceptable. Quantities of the starting materials used and the product produced in the manufacturing process have been stated and are acceptable.
2. The product chemistry data submitted corresponding to guideline 830.1670 (discussion of the formation of impurities) are acceptable. The origin of one major impurity [REDACTED] has been provided.
3. The product chemistry data submitted corresponding to guideline 830.1800 (enforcement analytical method) are satisfied.



Subject: Final Work Product: Mepiquat Chloride (PC code: 109101 DP
Barcode: D400267

Esther Williams to: Shaunta Hill
Cc: Ideliz Encarnacion, John Liccione

06/14/2012 03:54 PM

The HED work that you requested is now complete.

Here is the link to the signed PDF of the final document ==>

If you prefer the hard copy of this final document, it will be available for pick up for the next 2 weeks in the HED Records Center (S-10981).

Hours of Operation: Monday through Friday 10AM to Noon and 1PM to 3PM

Please contact OPP HED Records Management via email if you need assistance.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

Date: 10-May-2012

SUBJECT: Mepiquat Chloride: Impurities Discussion for New Technical Grade Active Ingredient. EPA Reg. No. 88781-R.

PC Code: 109101
Decision No.: 456565
Petition No.: NA
Risk Assessment Type: NA
TXR No.: NA
MRID No.: NA

DP Barcodes: D400267
Registration No.: 88781-R
Regulatory Action: Impurities Review
Case No.: NA
CAS No.: 24307-26-4
40 CFR: 180.384

FROM: Ideliz Negrón-Encarnación, Ph.D., Chemist, RAB VI
John Liccione, Ph.D., Toxicologist, RAB V
Health Effects Division (7509P)

THRU: Christine Olinger, Senior Chemist, RAB VII
Michael Metzger, Branch Chief, RAB V
Health Effects Division (7509P)

TO: Shaunta Hill, Risk Manager, RM 20
Registration Division (7505P)

I. Action Requested

Willowood Mepiquat Chloride, LLC has petitioned registration of an amended CSF for an alternate MUP (EPA Reg. No. 88781-R). The technical grade (TGAI) product of the active ingredient mepiquat chloride contained in 88781-R has a new impurity from a currently registered/cited TGAI (EPA Reg. No. 42570-73). The Registration Division (RD) has requested HED comment on the new impurity and their potential effects on the toxicity of the TGAI.

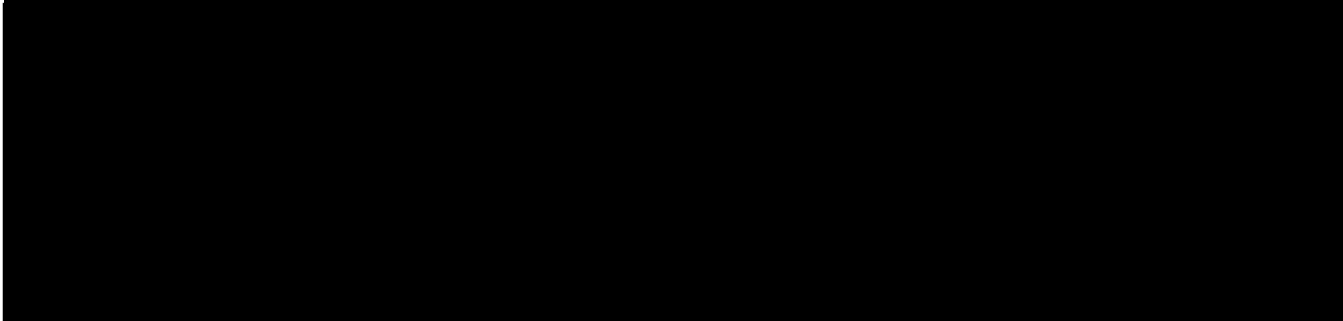
II. HED Conclusions

Although the chemical structure of the impurity is somewhat different to the parent, based on the absence of DEREK alerts, literature data indicating hazard concern, and the upper limit proposed by the registrant [REDACTED] there are no specific concerns for the toxicity at the levels anticipated.

Attachment: Confidential Appendix (2 pages)

Impurity Description

RD (I. Gairola, 03/13/2012, D396077) inquired about the impurity in the proposed confidential statement of formula for EPA Reg. No. 88781-R, which is listed in Table A-1. For mepiquat and the new impurity, HED used a toxicity prediction tool, DEREK (Nexus v. 2.0), to conduct a qualitative structure-activity relationship (SAR) analysis.



Hazard Characterization

Mepiquat Chloride

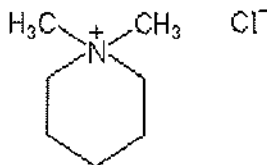
Reference: 11/22/99, M. Collantes, M. J. Nelson, A. Levy, D258184

The toxicity data show few significant biological effects at low doses and mild effects at higher doses. At higher dose levels, there were signs of neurotoxicity observed in rats and dogs as well as a decrease in body weight gains and food consumption. Dogs were the most sensitive species. In the developmental rabbit study, there were increased skeletal variations at 150 mg/kg/day (HDT), but not at 100 mg/kg/day. In the 2-generation rat study, there was retarded growth of the F₁ and F₂ pups at 499-627 mg/kg/day (HDT), but not at 147-164 mg/kg/day. Mepiquat chloride has an oral LD₅₀ in rats which falls into Toxicity Category II. For other acute parameters (dermal, inhalation, eye irritation or skin irritation), the Toxicity Categories are III or IV, and there are no inhalation or dermal studies of greater duration. Mepiquat chloride is not a dermal sensitizer, is not carcinogenic and is not mutagenic. There was no increase in susceptibility of fetuses or young animals demonstrated in the rat developmental, rabbit developmental or rat 2-generation reproduction studies.

The HIARC identified an appropriate toxicological endpoint for a single oral exposure and assigned an acute RfD of 0.6 mg/kg/day. This was based on the 1-year and 90-day studies in dogs administered mepiquat chloride by diet, in which, within 1-6 hours post-dosing, neurotoxicity signs were noted. The HIARC selected a chronic RfD of 0.6 mg/kg/day (NOAEL of 58.4 mg/kg/day and an UF of 100, based on the 1-year and 90-day dog studies described above, with the same endpoints as for the acute RfD). The HIARC selected a short- and

Confidential Appendix to D400267

intermediate-term dermal and inhalation endpoint for risk assessments purposes but established that either a long-term dermal or a long-term inhalation endpoint were not required.

Table A-2. Nomenclature of Mepiquat Chloride	
IUPAC Name	Chemical Structure
1,1-dimethylpiperidinium chloride	

Discussions and Conclusions

The DEREK report for mepiquat showed alerts for acute toxicity related to the quaternary ammonium but no systemic toxicity alerts were obtained. [REDACTED]

[REDACTED]. However, no DEREK alerts were displayed for the impurity. Further searches for toxicity information related to the impurity or chemical analogs were done but no relevant information was obtained.

Although the chemical structure of the impurity is somewhat different to the parent, based on the absence of DEREK alerts, literature data indicating hazard concern, and the upper limit proposed by the registrant [REDACTED] there are no specific concerns for the toxicity at the levels anticipated.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

SUBJECT: Product Chemistry Review of "Willowood Mepiquat Chloride Technical"
TGAI/MUP

DATE: 06/28/12

FROM: Indira Gairola Product Chemistry Team (A) 06/27/12
Technical Review Branch / Registration Division (7505P)

TO: Shaunta Hill/ Shaja Joyner PM 20
Fungicide Branch Registration Division (7505P)

DP BARCODE: 403186

DECISION NO.: 456565

REGISTRATION NO./FILE SYMBOL NO.: 88781-R

PRODUCT NAME: Willowood Mepiquat Chloride Technical

PC CODE: 109101

REGISTRANT: Willowood Mepiquat Chloride, LLC

USE: Fungicide

FOOD USE: Yes ☐ No ☒

MRID NUMBERS: 486308-01 through 486308-03

INTRODUCTION:

The applicant submitted an application for approval of the new manufacturing use product "Willowood Mepiquat Chloride Technical," which is not quite similar to the existing product "Technical Mepiquat Chloride" registered by Albaugh Inc. under EPA Reg. No. 42570-73. In support of the application, the applicant submitted Group A product chemistry data with MRID Nos. 486308-01 and 486308-02, and Group B product chemistry data with MRID No. 486308-03. The CSF for the basic formulation (dated 10/17/2011) was submitted for the product. The review for the subject product was completed by Indira Gairola on 03/13/12 for details please refer to DP BARCODE 396077.

SUMMARY OF FINDINGS:

There was some concern regarding series 830.1670 (discussion on the formation of impurities). The additional impurity stated on the basic CSF (dated 10/17/2011) was sent to HED to determine toxicity. It has been determined by HED that the additional impurity stated is not of significant toxicological concern although the structure of the impurity is somewhat different from the parent compound.

CONCLUSIONS:

It is determined the aforementioned impurity is not of toxicological concern although the structure of the impurity is somewhat different from the parent.
For details regarding this impurity please refer to the attached report dated 05/10/12 from Risk assessment Branch VII&RAB V.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

Date: 10-May-2012

SUBJECT: Mepiquat Chloride: Impurities Discussion for New Technical Grade Active Ingredient. EPA Reg. No. 88781-R.

PC Code: 109101

Decision No.: 456565

Petition No.: NA

Risk Assessment Type: NA

TXR No.: NA

MRID No.: NA

DP Barcodes: D400267

Registration No.: 88781-R

Regulatory Action: Impurities Review

Case No.: NA

CAS No.: 24307-26-4

40 CFR: 180.384

FROM: Ideliz Negrón-Encarnación, Ph.D., Chemist, RAB V
John Liccione, Ph.D., Toxicologist, RAB V
Health Effects Division (7509P)

THRU: Christine Olinger, Senior Chemist, RAB VII
Michael Metzger, Branch Chief, RAB V
Health Effects Division (7509P)

TO: Shaunta Hill, Risk Manager, RM 20
Registration Division (7505P)

I. Action Requested

Willowood Mepiquat Chloride, LLC has petitioned registration of an amended CSF for an alternate MUP (EPA Reg. No. 88781-R). The technical grade (TGAI) product of the active ingredient mepiquat chloride contained in 88781-R has a new impurity from a currently registered/cited TGAI (EPA Reg. No. 42570-73). The Registration Division (RD) has requested HED comment on the new impurity and their potential effects on the toxicity of the TGAI.

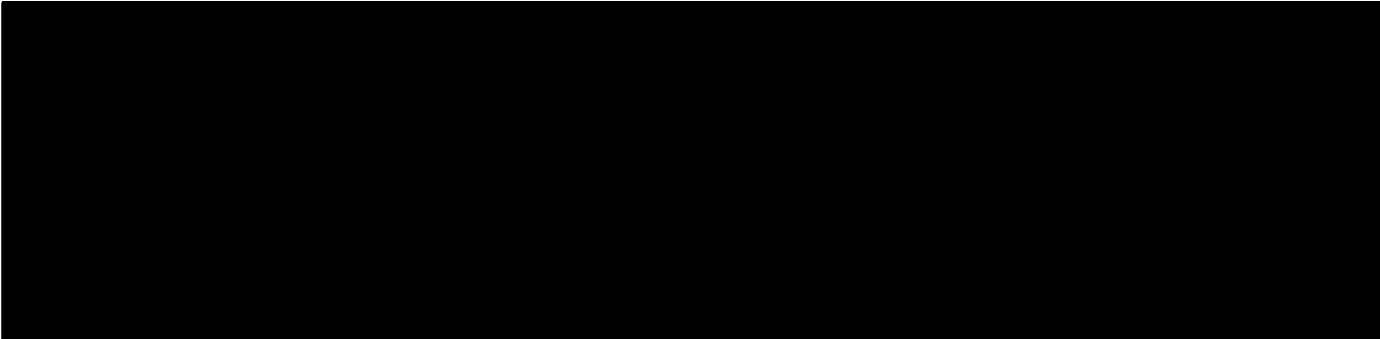
II. HED Conclusions

Although the chemical structure of the impurity is somewhat different to the parent, based on the absence of DEREK alerts, literature data indicating hazard concern, and the upper limit proposed by the registrant [REDACTED] there are no specific concerns for the toxicity at the levels anticipated.

Attachment: Confidential Appendix (2 pages)

Impurity Description

RD (I. Gairola, 03/13/2012, D396077) inquired about the impurity in the proposed confidential statement of formula for EPA Reg. No. 88781-R, which is listed in Table A-1. For mepiquat and the new impurity, HED used a toxicity prediction tool, DEREK (Nexus v. 2.0), to conduct a qualitative structure-activity relationship (SAR) analysis.



Hazard Characterization

Mepiquat Chloride

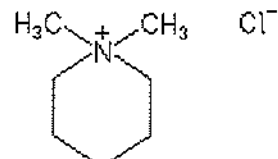
Reference: 11/22/99, M. Collantes, M. J. Nelson, A. Levy, D258184

The toxicity data show few significant biological effects at low doses and mild effects at higher doses. At higher dose levels, there were signs of neurotoxicity observed in rats and dogs as well as a decrease in body weight gains and food consumption. Dogs were the most sensitive species. In the developmental rabbit study, there were increased skeletal variations at 150 mg/kg/day (HDT), but not at 100 mg/kg/day. In the 2-generation rat study, there was retarded growth of the F₁ and F₂ pups at 499-627 mg/kg/day (HDT), but not at 147-164 mg/kg/day. Mepiquat chloride has an oral LD₅₀ in rats which falls into Toxicity Category II. For other acute parameters (dermal, inhalation, eye irritation or skin irritation), the Toxicity Categories are III or IV, and there are no inhalation or dermal studies of greater duration. Mepiquat chloride is not a dermal sensitizer, is not carcinogenic and is not mutagenic. There was no increase in susceptibility of fetuses or young animals demonstrated in the rat developmental, rabbit developmental or rat 2-generation reproduction studies.

The HIARC identified an appropriate toxicological endpoint for a single oral exposure and assigned an acute RfD of 0.6 mg/kg/day. This was based on the 1-year and 90-day studies in dogs administered mepiquat chloride by diet, in which, within 1-6 hours post-dosing, neurotoxicity signs were noted. The HIARC selected a chronic RfD of 0.6 mg/kg/day (NOAEL of 58.4 mg/kg/day and an UF of 100, based on the 1-year and 90-day dog studies described above, with the same endpoints as for the acute RfD). The HIARC selected a short- and

Confidential Appendix to D400267

intermediate-term dermal and inhalation endpoint for risk assessments purposes but established that either a long-term dermal or a long-term inhalation endpoint were not required.

Table A-2. Nomenclature of Mepiquat Chloride	
IUPAC Name	Chemical Structure
1,1-dimethylpiperidinium chloride	

Discussions and Conclusions

The DEREK report for mepiquat showed alerts for acute toxicity related to the quaternary ammonium but no systemic toxicity alerts were obtained. [REDACTED]

[REDACTED] However, no DEREK alerts were displayed for the impurity. Further searches for toxicity information related to the impurity or chemical analogs were done but no relevant information was obtained.

Although the chemical structure of the impurity is somewhat different to the parent, based on the absence of DEREK alerts, literature data indicating hazard concern, and the upper limit proposed by the registrant [REDACTED] there are no specific concerns for the toxicity at the levels anticipated.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

**TECHNICAL REVIEW BRANCH
SIMILARITY DETERMINATION**

03/JUL/2012

MEMORANDUM

Subject: Name of Pesticide Product: Willowood Mepiquat Chloride Technical
EPA Reg. No. /File Symbol: 88781-R
DP Barcode: D396078
Decision No: 456565
Action Code: R310
PC Code: 109101 (mepiquat chloride)

From: Eugenia McAndrew, Biologist
Technical Review Branch
Registration Division (7505P)

E. McAndrew
T.L. Toxicology

To: Shaunta Hill, RM Team 20
Fungicide Branch
Registration Division (7505P)

Applicant: Willowood Mepiquat Chloride, LLC
c/o Wagner Regulatory Associates, Inc.
P.O. Box 640
Hockessin, DE 19707

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Mepiquat chloride	98.6

<u>Other Ingredient(s):</u>	<u>1.4</u>
Total:	100.0%

ACTION REQUESTED: The Risk Manager requests: "Please review the attached label, CSF and data matrix submitted in support of a new TGA1 for acceptability. No acute tox was submitted. Also, please determine similarity to EPA Reg. No. 42750-73."

BACKGROUND: Willowood Mepiquat Chloride, LLC has applied for registration of Willowood Mepiquat Chloride Technical, EPA File Symbol 88781-R, claiming similarity to Technical Mepiquat Chloride, EPA Reg. No. 42750-73. Both products are technical grade for manufacturing use only. The registrant is using the cite-all method of data support to satisfy the acute toxicity data requirements. The submission includes a basic CSF dated October 17, 2011, a label, data matrix and company letter.

The TRB Product Chemistry Team reviewed the claim for similarity and concluded the following:

The subject product is not quite similar to the existing product "Technical Mepiquat Chloride" registered by Albaugh, Inc. under EPA Reg. No. 42750-73, the physico-chemical properties are different and the impurity profile is different. There is one impurity that is questionable. PM is requested to send this review to HED for evaluation of this impurity. (Gairola; D396077; EPA File Symbol 88781-R; 13/MAR/2012).

The action was sent to The Health Effects Division (HED) for comment on the impurity and the potential effects on the toxicity of the proposed product. HED completed its evaluation and concluded:

Although the chemical structure of the impurity is somewhat different to the parent, based on the absence of DEREK alerts, literature data indicating hazard concern, and the upper limit proposed by the registrant, there are no specific concerns for the toxicity at the levels anticipated. (Negron-Encarnacion, I. and Liccione, J.; EPA File Symbol 88781-R; D400267; 10/MAY/2012).

RECOMMENDATIONS:

1. Based on a comparison of the CSFs for the proposed and cited products and the HED analysis of the impurity profile of the proposed product, TRB has determined that the proposed product, 88781-R, and the cited product, 42750-73, are substantially similar.
2. After searching the OPP electronic file database, TRB was unable to locate any acute toxicity data for 42750-73. Therefore, an acute toxicity profile for 88781-R cannot be generated.
3. Based on the label for 42750-73, the sigi recommends that the proposed product u product.

FB note.

Acute tox profile for 42750-73 is available under 51036-187 7/23/12

RNING." TRB eling as the cited

4. This memorandum pertains only to the decision concerning whether the subject product is similar to the cited product from an acute toxicological view point. For the purposes of this action, TRB has made no further determination of the adequacy of the toxicological data base or the precautionary label of the cited product.
5. The basic CSF submitted for 88781-R has been accepted by the TRB Product Chemistry Team (Gairola; D403186; EPA File Symbol 88781-R; 02/JUL/2012).

Memorandum

Date: 05 / 17 / 12

To: PM 20, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission
☐ partially accepted submission
☐ rejected submission

resubmission

Administrative Materials



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

CERTIFIED MAIL

MAR 26 2012

OPP Decision Number: 456565

Applicant

Willowood Mepiquat Chloride, LLC
1600 NW Garden Valley Blvd.
Suite 120
Roseburg, OR 97471

Mailed to Agent

Catherine Byrd
Wagner Regulatory Associates, Inc.
P.O. Box 640
7217 Lancaster Pike, Suite A
Hockessin, DE 19707

Subject: Application Deficiency
Product Name: Willowood Mepiquat Chloride Technical
EPA File Symbol: 88781-R
Application Date: 10/17/2011
EPA Receipt Date: 10/18/2011

Dear Ms. Byrd,

The Agency has received and begun its in-depth review of the subject application and has determined that it is incomplete or that further information is needed. This letter is a written notification of those deficiencies and identifies your options under 40 CFR 152.105 and Section 33 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), also known as the Pesticide Registration Improvement Renewal Act (PRIA 2). Your options under 40 CFR 152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter. Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR 152.105:

Pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the application, or notifying the Agency of the date on

Page 2 of 2

Decision No. 456565

application as if you had withdrawn it. Withdrawal concludes the Agency's review of your application. Any subsequent submission of the same application must then be submitted as a new application with a new deadline for EPA to make a determination on your application and subject to a new registration service fee.

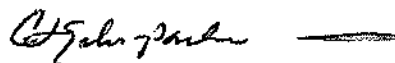
The deficiencies identified in the Agency's review at this time are as follows.

1. The product chemistry data submitted corresponding to guideline 830.1620 (description of production process) are not acceptable. Quantities of the starting materials used and the product produced in the manufacturing process were not given.
2. The product chemistry data submitted corresponding to guideline 830.1670 (discussion of the formation of impurities) are not acceptable. The origin of one major impurity [REDACTED] was not provided.
3. The product chemistry data submitted corresponding to guideline 830.1800 (enforcement analytical method) are not acceptable. The method was not validated for linearity and accuracy.

Further review of your application and your response to the deficiencies may identify additional deficiencies and you will be so informed.

Please respond to this letter within 75 days of the stamped date by contacting Shaunta Hill (hill.shaunta@epa.gov, 703-347-8961) or Cynthia Giles-Parker (giles-parker.cynthi@epa.gov, 703-305-7740) during the hours of 9 am to 4 pm EST with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



Cynthia Giles-Parker
Acting Product Manager, Team 20
Registration Division



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 15, 2012

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

WAGNER REGULATORY ASSOCIATES, INC
WILLOWOOD MEPIQUAT CHLORIDE, LLC
PO.BOX : 640
HOCKESSIN, DE 19707

Report of Analysis for Compliance with PR Notice 11-3

Thank you for your submittal of 04-MAY-12. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-3. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Section 3

S: 818341

Resubmission: ☒ Yes ☐ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: New Registration

Billable: ☐ Yes ☒ No

Company: 88781 WILLOWOOD MEPIQUAT CHLORIDE, LLC

V

Risk Manager: Registration Division, Risk Management Team 20

Product #: 88781-R

Product Name: WILLOWOOD MEPIQUAT CHLORIDE TECHNICAL

Override:

Me Too
Section3: 42750-73

Me Too
Product Name: TECHNICAL MEPIQUAT CHLORIDE

Application Date: 03-May-2012



OPP Rec'd Date: 04-May-2012



Front End Date: 07-May-2012



Risk Manager Send Date: 07-May-2012



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

response to application deficiency letter of 3/26/12

New Ingredient

Request Date

New Ingredient

Received Date

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

Study

View/Edit

48821300

WRA

May 3, 2012

Document Processing Desk
ATTN: Shaja Joyner, PM 20
Registration Division
U.S. Environmental Protection Agency
Office of Pesticide Programs (7504P)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

Wagner Regulatory Associates, Inc.
P.O. Box 640
7217 Lancaster Pike, Suite A
Hockessin, Delaware 19707

Dear Ms. Joyner,

Subject: Application Deficiency Response
Willowood Mepiquat Chloride Technical
EPA File Symbol: 88781-R
Decision Number: 456565

In response to an application deficiency letter dated March 26, 2012 from the Agency, Wagner Regulatory Associates, Inc. (agent for Willowood Mepiquat Chloride, LLC) respectfully submits the responses below.

1. *The product chemistry data submitted corresponding to the guideline 830.1620 (description of production process) are not acceptable. Quantities of starting materials used and the product produced in the manufacturing process were not given.*

The product chemistry data has been revised to include this information and three copies are enclosed with this response.

2. *The product chemistry data submitted corresponding to guideline 830.1670 (discussion of the formation of impurities) are not acceptable. The origin of one major impurity (██████) was not provided.*

The product chemistry data has been revised to include this information and three copies are enclosed with this response.


3. *The product chemistry data submitted corresponding to guideline 830.1800 (enforcement analytical method) are not acceptable. The method was not validated for linearity and accuracy.*

According to the laboratory that conducted this study, linearity of the determination of the active is on page 29 (Section 4.1.8). In regard to accuracy, this parameter is not applicable to the active constituent. Accuracy (a.k.a. recovery) is done by spiking (adding) known amount of the target analyte to the test solutions and then determining the amount found and comparing to the added amount. This procedure is not possible for the active because the solutions already contain >98% of the active. Accuracy/recovery is applicable only to impurities and formulated products.

In support of this response, revised product chemistry data and a data transmittal document are enclosed.

If you have any questions, please contact the undersigned at catherine@wagnerreg.com or (302) 635-7283.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Catherine M. Byrd". The signature is fluid and cursive, with the first name being the most prominent.

Catherine M. Byrd
Agent for Willowood Mepiquat Chloride, LLC

Cc: Shaunta Hill, USEPA

DATA TRANSMITTAL DOCUMENT

1. Name and Address of Submitter

Willowood Mepiquat Chloride, LLC
c/o Wagner Regulatory Associates
PO Box 640
Hockessin, DE 19707

2. Regulatory Action In Support Of Which This Package Is Submitted

Response to Application Deficiency
Willowood Mepiquat Chloride Technical
EPA File Symbol 88781-R
Decision No. 456565

3. Transmittal Date

May 3, 2012

4. List of Submitted Studies

48821301

Vol. 1: Wagner Regulatory Associates, Inc. (2011) Willowood Mepiquat Chloride
Technical-Product Identity and Composition, Description of Beginning Materials,
Manufacturing Process, and Discussion of Formation of Impurities. Willowood
Mepiquat Chloride, LLC, Roseburg, OR. Non-confidential portion 6 pages,
Confidential portion 40 pages.

Company Official: Catherine M. Byrd
Name



Signature

Company Name: Wagner Regulatory Associates, Inc.
Agent for Willowood Mepiquat Chloride, LLC

Company Contact: Catherine M. Byrd
Name

(302) 635-7283
Phone

Approved PRIA
correction

Recommendation of Division Directors Negotiated Due Dates			
Decision #: 456565		Registration #: 88781-R	
		Petition #:	
<input type="checkbox"/> See page 2 for additional registration entries			
Chemical Name: Mepiquat chloride			
Fee Category: R.310		PRIA Decision Time Frame: 6 months	
Submitted by: Shaunta Hill		Branch: OCSPP/OPP/RD	Date: 05/23/2012
Company: Willowood Mepiquat Chloride, LLC			
Original PRIA Due Date: 05/08/2012		Proposed New PRIA Due Date: 09/05/2012	
Previous Negotiated Due Dates:			
Is the "Fix" in-house? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n/a		If not, date "Fix" expected:	
Negotiated Due Date Reason:			
Additional Data Required	<input type="checkbox"/> Product Chemistry	<input type="checkbox"/> Toxicology	<input type="checkbox"/> Acute Tox
	<input type="checkbox"/> Efficacy	<input type="checkbox"/> Ecological	<input type="checkbox"/> Residue
Data Deficiencies	<input type="checkbox"/> Product Chemistry	<input type="checkbox"/> Acute Tox	<input type="checkbox"/> Efficacy
	<input type="checkbox"/> Environmental	<input type="checkbox"/> Ecological	<input type="checkbox"/> Labeling
Late Risk Assessment	<input type="checkbox"/> Human Health	<input type="checkbox"/> Ecological	<input type="checkbox"/> Residue
Interim Consideration	<input type="checkbox"/> Agency Initiated	<input type="checkbox"/> Registrant Initiated	<input type="checkbox"/> Toxicology
<input type="checkbox"/> CSF	<input type="checkbox"/> Public Process	<input type="checkbox"/> Risk Issues Environmental	<input type="checkbox"/> Risk Issues Human Health
<input type="checkbox"/> Impurities Review	<input type="checkbox"/> Label	<input type="checkbox"/> Administrative-FR Notice	<input checked="" type="checkbox"/> Other - Comment Field
Summary of Deficiency Type(s): <input type="checkbox"/> Not Submitted (N) <input type="checkbox"/> Deficiencies (D)			
Product Chemistry: <input type="checkbox"/> Acute Tox: <input type="checkbox"/> Efficacy: <input type="checkbox"/> Labeling: <input type="checkbox"/> Ecological Data: <input type="checkbox"/> Other (describe): <input type="checkbox"/>			
Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates): A PRIA extension to September 5, 2012 was agreed to by the applicant on 3/22/12. An extension form was submitted (4/22/12) with the incorrect proposed extension date. This re-submission serves to correct that.			
"75 Day" Letter sent? <input type="checkbox"/> Yes, Date sent <input type="checkbox"/> No and reason for none? Add comments on page 2			
Rationale for Proposed Due Date:			
Registrant notified that this is the last negotiation? <input type="checkbox"/> Yes <input type="checkbox"/> Not Applicable			
Approve: <input checked="" type="checkbox"/>		Disapprove: <input type="checkbox"/>	
If disapproved, action to be taken:			
OD or DOD Signature: CN=Marty Monel/OU=DC/O=USEPA/C=US			Date: 05/23/2012

Decision #:	Registration #:	Petition #:

Issue(s) (describe in detail):

This form is submitted to correct the PRIA extension request.
The approved form listed the incorrect negotiation date (8/5/12). The correct extension date as noted on the company's agreement letter is 9/5/2012.

Comment(s):

Audit Trail for

Recommendation of Division Directors Negotiated Due Dates

PDF Name: PRIAv4a.pdf

Form Number: PRIA

Document Identifier: PRIA-12144062903-SH

SUBMITTED on 05/23/2012 at 06:57:08 AM by CN=Shaunta Hill/OU=DC/O=USEPA/C=US

APPROVED on 05/23/2012 at 09:28:03 AM by CN=Cynthia Giles-Parker/OU=DC/O=USEPA/C=US

APPROVED on 05/23/2012 at 10:25:38 AM by CN=Dan Rosenblatt/OU=DC/O=USEPA/C=US

APPROVED AND COMPLETED on 05/23/2012 at 10:32:48 AM by CN=Marty Monell/OU=DC/O=USEPA/C=US

Recommendation of Division Directors Negotiated Due Dates			
Decision #: 456565		Registration #: 88781-R	
		Petition #:	
<input type="checkbox"/> See page 2 for additional registration entries			
Chemical Name: Mepiquat Chloride			
Fee Category: R.310		PRIA Decision Time Frame: 6 months	
Submitted by: Shaunta Hill		Branch: OCSPP/OPP/RD	Date: 04/02/2012
Company: Willowood Mepiquat Chloride, LLC			
Original PRIA Due Date: 05/08/2012		Proposed New PRIA Due Date: 08/05/2012 incorrect date, should be 9/5/12	
Previous Negotiated Due Dates:			
Is the "Fix" in-house?		If not, date "Fix" expected:	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> n/a			
Negotiated Due Date Reason:			
Additional Data Required	<input type="checkbox"/> Product Chemistry	<input type="checkbox"/> Toxicology	<input type="checkbox"/> Acute Tox
	<input type="checkbox"/> Efficacy	<input type="checkbox"/> Ecological	<input type="checkbox"/> Residue
Data Deficiencies	<input type="checkbox"/> Product Chemistry	<input type="checkbox"/> Acute Tox	<input type="checkbox"/> Efficacy
	<input type="checkbox"/> Environmental	<input type="checkbox"/> Ecological	<input type="checkbox"/> Labeling
Late Risk Assessment	<input type="checkbox"/> Human Health	<input type="checkbox"/> Ecological	<input type="checkbox"/> Toxicology
Interim Consideration	<input type="checkbox"/> Agency Initiated	<input type="checkbox"/> Registrant Initiated	<input type="checkbox"/> Other
<input type="checkbox"/> CSF	<input type="checkbox"/> Public Process	<input type="checkbox"/> Risk Issues Environmental	<input type="checkbox"/> Risk Issues Human Health
<input checked="" type="checkbox"/> Impurities Review	<input type="checkbox"/> Label	<input type="checkbox"/> Administrative-FR Notice	<input type="checkbox"/> Other - Comment Field
Summary of Deficiency Type(s): <input type="checkbox"/> Not Submitted (N) <input type="checkbox"/> Deficiencies (D)			
Product Chemistry: <input type="checkbox"/> Acute Tox: <input type="checkbox"/> Efficacy: <input type="checkbox"/> Labeling: <input type="checkbox"/> Ecological Data: <input type="checkbox"/> Other (describe): <input type="checkbox"/>			
Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):			
The company's agent was contacted on 3/22/12 noting that an impurity concern was raised during the product chemistry review. The company has agreed to an extension of 120 days to cover time needed for the HED review.			
"75 Day" Letter sent? <input type="checkbox"/> Yes, Date sent <input type="checkbox"/> No and reason for none? <i>Add comments on page 2</i>			
Rationale for Proposed Due Date: 120 days is needed for the HED impurity team review.			
Registrant notified that this is the last negotiation? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not Applicable			
Approve: <input checked="" type="checkbox"/>		Disapprove: <input type="checkbox"/>	
If disapproved, action to be taken:			
OD or DOD Signature: CN=Marty Monell/OU=DC/O=USEPA/C=US			Date: 04/04/2012

Decision #:	Registration #:	Petition #:
Issue(s) (describe in detail):		
Comment(s):		

Audit Trail for

Recommendation of Division Directors Negotiated Due Dates

PDF Name: PRIAv4a.pdf

Form Number: PRIA

Document Identifier: PRIA-12093071323-SH

SUBMITTED on 04/02/2012 at 07:32:00 AM by CN=Shaunta Hill/OU=DC/O=USEPA/C=US

APPROVED on 04/02/2012 at 08:52:42 AM by CN=Cynthia Giles-Parker/OU=DC/O=USEPA/C=US

APPROVED on 04/03/2012 at 04:46:15 PM by CN=Lois Rossi/OU=DC/O=USEPA/C=US

APPROVED AND COMPLETED on 04/04/2012 at 07:16:42 AM by CN=Marty Monell/OU=DC/O=USEPA/C=US

March 22, 2012

Document Processing Desk
ATTN: Shaja Joyner, PM 20
Registration Division
U.S. Environmental Protection Agency
Office of Pesticide Programs (7504P)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501



Wagner Regulatory Associates, Inc.
P.O. Box 640
7217 Lancaster Pike, Suite A
Hockessin, Delaware 19707

Dear Ms. Joyner,

**Subject: Agreement to 120-day PRIA extension for
Willowood Mepiquat Chloride Technical
EPA File Symbol: 88781-R
Decision Number: 456565**

Ms. Shaunta Hill of USEPA informed Wagner Regulatory Associates, Inc. (agent for Willowood Mepiquat Chloride, LLC) via telephone on March 22, 2012 that an unknown impurity was identified during the product chemistry review. Willowood Mepiquat Chloride, LLC agrees to the 120-day PRIA extension which will allow the Health Effects Division (HED) to further evaluate this impurity. The new PRIA date will be September 5, 2012.

If you have any questions, please contact the undersigned at catherine@wagnerreg.com or (302) 635-7283.

Respectfully submitted,

A handwritten signature in black ink that reads "Catherine M. Byrd".

Catherine M. Byrd
Agent for Willowood Mepiquat Chloride, LLC

Cc: Shaunta Hill, USEPA

SENDER: COMPLETE THIS SECTION	COMPLETE THIS SECTION ON DELIVERY
<p><input checked="" type="checkbox"/> Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.</p> <p><input checked="" type="checkbox"/> Print your name and address on the reverse so that we can return the card to you.</p> <p><input checked="" type="checkbox"/> Attach this card to the back of the mailpiece, or on the front if space permits.</p>	<p>A. Signature <input type="checkbox"/> Agent <input type="checkbox"/> Addressee <i>Cheryl Wagner</i></p>
<p>f. Article Addressed to: D# 456565 Ms. Catherine Byrd Wagner Regulatory Associates, Inc. P.O. Box 640 7217 Lancaster Pkwy, Suite A Hockessin, Delaware 19707</p>	<p>B. Received by (Printed Name) C. Date of Delivery <i>Cheryl Wagner</i> 3/30/12</p>
<p>2. Article Number (Transfer from service label)</p>	<p>D. Is delivery address different from item 1? <input type="checkbox"/> Yes <input type="checkbox"/> No If YES, enter delivery address below:</p>
<p>PS Form 3811, February 2004</p>	<p>Domestic Return Receipt 102595-02-M-1</p>

U.S. Postal Service™	
CERTIFIED MAIL™ RECEIPT	
(Domestic Mail Only; No Insurance Coverage Provided)	
For delivery information, visit our website at www.usps.com	
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<div style="display: flex; justify-content: space-between;"> <div>Postage</div> <div>\$</div> </div> <div style="display: flex; justify-content: space-between;"> <div>Certified Fee</div> <div></div> </div> <div style="display: flex; justify-content: space-between;"> <div>Return Receipt Fee (Endorsement Required)</div> <div></div> </div> <div style="display: flex; justify-content: space-between;"> <div>Restricted Delivery Fee (Endorsement Required)</div> <div></div> </div> <div style="display: flex; justify-content: space-between;"> <div>Total Postage & Fees</div> <div>\$</div> </div>	<div style="text-align: center; font-size: 2em; transform: rotate(-45deg);">MAR 2 2012</div> <div style="text-align: center; font-size: 0.8em;">Postmark Here</div>
<p>Sent To: <i>Catherine Byrd - Wagner Regulatory</i></p> <p>Street, Apt. No., or PO Box No.: <i>P.O. Box 640 7217 Lancaster Pkwy, Suite A</i></p> <p>City, State, ZIP+4: <i>Hockessin, Delaware 19707</i></p>	
<p>PS Form 3800, August 2006 See Reverse for Instructions</p>	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

CERTIFIED MAIL

MAR 26 2012

OPP Decision Number: 456565

Applicant

Willowood Mepiquat Chloride, LLC
1600 NW Garden Valley Blvd.
Suite 120
Roseburg, OR 97471

Mailed to Agent

Catherine Byrd
Wagner Regulatory Associates, Inc.
P.O. Box 640
7217 Lancaster Pike, Suite A
Hockessin, DE 19707

Subject: Application Deficiency
Product Name: Willowood Mepiquat Chloride Technical
EPA File Symbol: 88781-R
Application Date: 10/17/2011
EPA Receipt Date: 10/18/2011

Dear Ms. Byrd,

The Agency has received and begun its in-depth review of the subject application and has determined that it is incomplete or that further information is needed. This letter is a written notification of those deficiencies and identifies your options under 40 CFR 152.105 and Section 33 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), also known as the Pesticide Registration Improvement Renewal Act (PRIA 2). Your options under 40 CFR 152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter. Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR 152.105:

Pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the application, or notifying the Agency of the date on

Page 2 of 2

Decision No. 456565

application as if you had withdrawn it. Withdrawal concludes the Agency's review of your application. Any subsequent submission of the same application must then be submitted as a new application with a new deadline for EPA to make a determination on your application and subject to a new registration service fee.

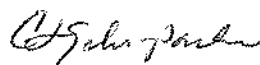
The deficiencies identified in the Agency's review at this time are as follows.

1. The product chemistry data submitted corresponding to guideline 830.1620 (description of production process) are not acceptable. Quantities of the starting materials used and the product produced in the manufacturing process were not given.
2. The product chemistry data submitted corresponding to guideline 830.1670 (discussion of the formation of impurities) are not acceptable. The origin of one major impurity [REDACTED] was not provided.
3. The product chemistry data submitted corresponding to guideline 830.1800 (enforcement analytical method) are not acceptable. The method was not validated for linearity and accuracy.

Further review of your application and your response to the deficiencies may identify additional deficiencies and you will be so informed.

Please respond to this letter within 75 days of the stamped date by contacting Shaunta Hill (hill.shaunta@epa.gov, 703-347-8961) or Cynthia Giles-Parker (giles-parker.cynthi@epa.gov, 703-305-7740) during the hours of 9 am to 4 pm EST with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



Cynthia Giles-Parker
Acting Product Manager, Team 20
Registration Division



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

SUBJECT: Product Chemistry Review of "Willowood Mepiquat Chloride Technical"
TGAI/MUP

DATE: 03/13/12

FROM: Indira Gairola Product Chemistry Team
Technical Review Branch / Registration Division (7505P)

TO: Shaunta Hill/ Shaja Joyner PM 20
Fungicide Branch Registration Division (7505P)

DP BARCODE: 396077

DECISION NO.: 456565

REGISTRATION NO./FILE SYMBOL NO.: 88781-R

PRODUCT NAME: Willowood Mepiquat Chloride Technical

PC CODE: 109101

REGISTRANT: Willowood Mepiquat Chloride, LLC

USE: Fungicide

FOOD USE: Yes [] No [X]

MRID NUMBERS: 486308-01 through 486308-03

INTRODUCTION:

The applicant submitted an application for approval of the new manufacturing use product "Willowood Mepiquat Chloride Technical," which is not quite similar to the existing product "Technical Mepiquat Chloride" registered by Albaugh Inc. under EPA Reg. No. 42570-73. In support of the application, the applicant submitted Group A product chemistry data with MRID Nos. 486308-01 and 486308-02, and Group B product chemistry data with MRID No. 486308-03. The CSF for the basic formulation (dated 10/17/2011) was submitted for the product. The Primary review was done by Summitec Corporation, 9724 Kingston Pike, Suite 602 Knoxville, Tennessee Task Order No. 3-A-11. TRB has been asked to determine the acceptability of the product chemistry data and basic CSF.

BARCODE: 396077; FILE SYMBOL No.: 88781-R; PRODUCT: Willowood Mepiquat Chloride Technical

SUMMARY OF FINDINGS:

1. Group A guidelines:

830.1550 (product identity & composition)

The submitted data are acceptable. The active ingredient and impurities were adequately described (MRID 486308-01 and CSF). The concentration of the active ingredient on the CSF (98.6%, nominal) matches that on the label and is the average derived from the 5-batch preliminary analysis (98.6%, MRID 486308-02). The product label does not state that the product is for manufacturing use only.

830.1600 (description of materials used to produce the product)

The submitted data are acceptable. MSDSs of all the starting materials, and their suppliers and specifications are provided in the study (MRID 486308-01). The information presented meets the data requirements for 40 CFR 158.160.

830.1620 (description of production process)

The submitted data are not acceptable (MRID 486308-01). Description of the production process, a flow chart, and quality control measures were provided. However, quantities of the starting materials used and the product produced in the manufacturing process were not given. The information presented does not meet the data requirements for 40 CFR 158.160.

830.1670 (discussion on the formation of impurities)

The submitted data are not acceptable. [REDACTED] impurities [REDACTED] and [REDACTED] were present at levels greater than 0.1% (MRID 486308-01). The origin of the impurity [REDACTED] was not provided. The information presented does not meet the data requirements for 40 CFR 158.167.

830.1700 (preliminary analysis)

The submitted data are acceptable. Results are presented for a five-batch analysis (MRID 486308-02) using HPLC-UV and with external standard calibration. The nominal concentrations of the A.I. were: 98.6, 98.6, 98.4, 98.7 and 98.7% (average 98.6%). The information presented meets the data requirements for 40 CFR 158.170.

BARCODE: 396077; FILE SYMBOL No.: 88781-R; PRODUCT: Willowood Mepiquat Chloride Technical

830.1750 (certified limits)

The submitted data are acceptable. The certified limits for the AI (Upper limit: 100.0% and Lower limit: 95.6%; from CSF) are within EPA's Standard Certified Limits. The information presented meets the data requirements for 40 CFR 158.175.

830.1800 (enforcement analytical method)

The submitted data are not acceptable. The analytical method used for verification of the certified limits for the AI is HPLC-UV and with external standard calibration (MRDI 486308-02). The method was not validated for linearity and accuracy. The information presented does not meet the data requirements for 40 CFR 158.180.

2. Group B guidelines (physical-chemical properties):

Acceptable product chemistry data were provided for 830 series group B guidelines for color, physical state, odor, stability to normal and elevated temperatures, oxidation/reduction, pH, UV/visible absorption, density, partition coefficient, water solubility, and vapor pressure. No data were submitted for studies to fulfill guidelines 830.6317 (storage stability) and 830.6320 (corrosion characteristics). The registrant states that these tests have been initiated. It is recommended that the observations should be made at 0, 3, 6, 9, and 12 month intervals. No data were submitted for stability to metals and metal ions, flammability, explosability, miscibility, dielectric breakdown voltage, viscosity, melting point, dissociation constants and boiling point on the basis that they were not relevant for the product.

CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for Technical TGAI (produced by Willowood Mepiquat Chloride, LLC) and has concluded that:

1. The product chemistry data submitted corresponding to guidelines 830.1550 (product identity and composition), 830.1600 (description of the materials used to produce the product), 830.1700 (preliminary analysis) and 830.1750 (certified limits) are acceptable.
2. The product chemistry data submitted corresponding to guideline 830.1620 (description of production process) are not acceptable. Quantities of the starting materials used and the product produced in the manufacturing process were not given.
3. The product chemistry data submitted corresponding to guideline 830.1670 (discussion of the formation of impurities) are not acceptable. The origin of one major impurity [REDACTED] was not provided.

BARCODE: 396077; FILE SYMBOL No.: 88781-R; PRODUCT: Willowood Mepiquat Chloride Technical

4. The product chemistry data submitted corresponding to guideline 830.1800 (enforcement analytical method) are not acceptable. The method was not validated for linearity and accuracy.
5. The proposed basic CSF for the basic formulation is acceptable. The nominal concentrations of the active ingredient and other ingredients on the product label match those on the CSF. Lower limits for the impurities should not be included on the CSF.
6. The product chemistry data submitted corresponding to 830 series Group B (physical-chemical properties) are acceptable. One-year "Storage Stability" and "Corrosion Characteristics" studies are in progress.
7. The subject product is not quite similar to the existing product "Technical Mepiquat Chloride" registered by Albaugh Inc. under EPA Reg. No. 42570-73, the physico-chemical properties are different and the impurity profile is different. There is one impurity that is questionable ; (comparative table of impurities is attached to this review along with the structure of the impurity).
PM is requested to send this review to HED for evaluation of this impurity. Please refer to page #21 of this review.

DATA EVALUATION RECORD

MEPIQUAT CHLORIDE (Willowood Mepiquat Chloride Technical)

STUDY TYPES: Product Identity and Composition (OCSP 830.1550)
Description of Materials Used to Produce the Product (OCSP 830.1600)
Description of the Production Process (OCSP 830.1620)
Discussion of Formation of Impurities (OCSP 830.1670)
Preliminary Analysis (OCSP 830.1700)
Certified Limits (OCSP 830.1750)
Enforcement Analytical Method (OCSP 830.1800)
Physical and Chemical Characteristics (OCSP 830.6302-830.7950)

MRIDs 486308-01 through 486308-03

Prepared for
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Summitec Corporation
9724 Kingston Pike, Suite 602
Knoxville, Tennessee 37922

Task Order No. 3-A-159

Primary Reviewer:
Maolian Chen, Ph.D.

Signature: Maolian Chen, AE
Date: MAR 05 2012

Secondary Reviewers:
Dennis Opresko, Ph.D.

Signature: Dennis Opresko
Date: MAR 05 2012

Robert H. Ross, M.S., Program Manager

Signature: Robert H. Ross
Date: MAR 05 2012

Quality Assurance:
Jennifer Goldberg, B.S.

Signature: Jennifer Goldberg
Date: MAR 05 2012

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

BARCODE: 396077; FILE SYMBOL No.: 88781-R; PRODUCT: Willowood Mepiquat Chloride Technical

830.1550. Product identity & composition: (MRID No. 486308-01)

Common Name: Mepiquat Chloride

Chemical name (CAS): 1,1-dimethylpiperidinium chloride

(IUPAC): 1,1-dimethylpiperidinium chloride

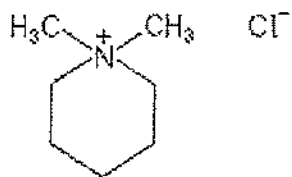
CAS No.: 24307-26-4

PC Code No.: 109101

Empirical Formula: $C_7H_{16}ClN$

Molecular Weight: 149.66 g/mole

Structural Formula:



BARCODE: 396077; FILE SYMBOL No.: 88781-R; PRODUCT: Willowood Mepiquat Chloride Technical

Table I. Manufacturing and Impurity Data for Technical TGA1 "Willowood Mepiquat Chloride Technical."				
GLN	Requirement	MRID	Status	Details and/or Deficiency
830.1550	Product Identity & Composition	486308-01	A	Adequately described.
830.1600	Description of materials used to produce the product	486308-01	A	MSDS sheets were provided for the starting materials.
830.1620	Description of production process	486308-01	U	No information was provided for the quantities of the starting materials used and amount of product produced.
830.1670	Discussion on the formation of impurities	486308-01	U	The origin of the impurity [REDACTED] was not provided.
830.1700	Preliminary analysis	486308-02	A	Five-batch analysis of the AI by HPLC-UV
830.1750	Certified limits	CSF (10/17/2011)	A	The certified limits for the AI are within EPA's Standard Certified Limits.
830.1800	Enforcement analytical method	486308-02	U	The AI and one major impurity were quantified by HPLC-UV with external calibration. The method was not validated for linearity and accuracy.
A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress; U = Up-grade (additional information required);				

BARCODE: 396077; FILE SYMBOL No.: 88781-R; PRODUCT: Willowood Mepiquat Chloride Technical

830 Series Subgroup B (Physical-Chemical Properties)

Table 2: Physical and Chemical Properties of: Technical TGAI "Willowood Mepiquat Chloride Technical."				
GLN	Requirement	MRID	Status	Result or Deficiency
830.6302	Color	486308-03	A	Off-white
830.6303	Physical state	486308-03	A	Solid
830.6304	Odor	486308-03	A	Moderate to strong
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	486308-03	A	Stable for two weeks at ambient temperature and at 54 °C. Tests for stability to metals and metal ions are not applicable as the product will not contact metals or metal ions.
830.6314	Oxidation/reduction: chemical incompatibility	486308-03	A	The product was tested with water, 5% ammonium phosphate, iron powder, 5% potassium permanganate and gasoline. Refer to Page 12-13 in MRID 486308-03 for results.
830.6315	Flammability	486308-03	NA	The product is a solid and contains no flammable ingredients.
830.6316	Explosibility	486308-03	NA	The product does not contain explosive ingredients.
830.6317	Storage stability	486308-03	I	In progress
830.6319	Miscibility	486308-03	NA	The product is not intended for dissolution in hydrocarbon solvents.
830.6320	Corrosion characteristics	486308-03	I	In progress
830.7000	pH	486308-03	A	5.94 (1% solution)
830.7050	UV/Visible absorption	486308-03	A	The product was tested under acidic, neutral and basic conditions for UV/Vis absorption. Refer to Table II and III on Page 14-15 of MRID 486308-03 for results.
830.7100	Viscosity	486308-03	NA	The product is a solid.
830.7200	Melting point	486308-03	NA	The product decomposes before melting (from literature).
830.7220	Boiling point	486308-03	NA	The product is a solid.
830.7300	Density	486308-03	A	1.317 g/cm ³ (tested via gas pycnometer) 0.588 g/cm ³ (tested via tap densitometer)
830.7370	Dissociation constants in water (DC)	486308-03	NA	The product is a salt.
830.7550	Partition coefficient	486308-03	A	Log P = -3.55 at pH of 7 and 20 °C (from literature).
830.7840	Water solubility	486308-03	A	500,000 mg/L at 20 °C (from literature)
830.7950	Vapor pressure	486308-03	A	1.00 × 10 ⁻⁵ mPa (from literature)

BARCODE: 396077; FILE SYMBOL No.: 88781-R; PRODUCT: Willowood Mepiquat Chloride Technical

A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress ;
U = Up-grade (additional information required); W = waivers

830.1800 (enforcement analytical method)

The analytical method employed to quantify the active ingredient is HPLC-UV with external standard calibration. FTIR and MS were used for identification of the AI. The details are presented in MRID 486308-02. The method was validated for specificity and precision for the determination of AI. The method was not validated for linearity and accuracy. No method validation information (except limit of detection) was provided for quantification of the impurities (MRID 486308-02).

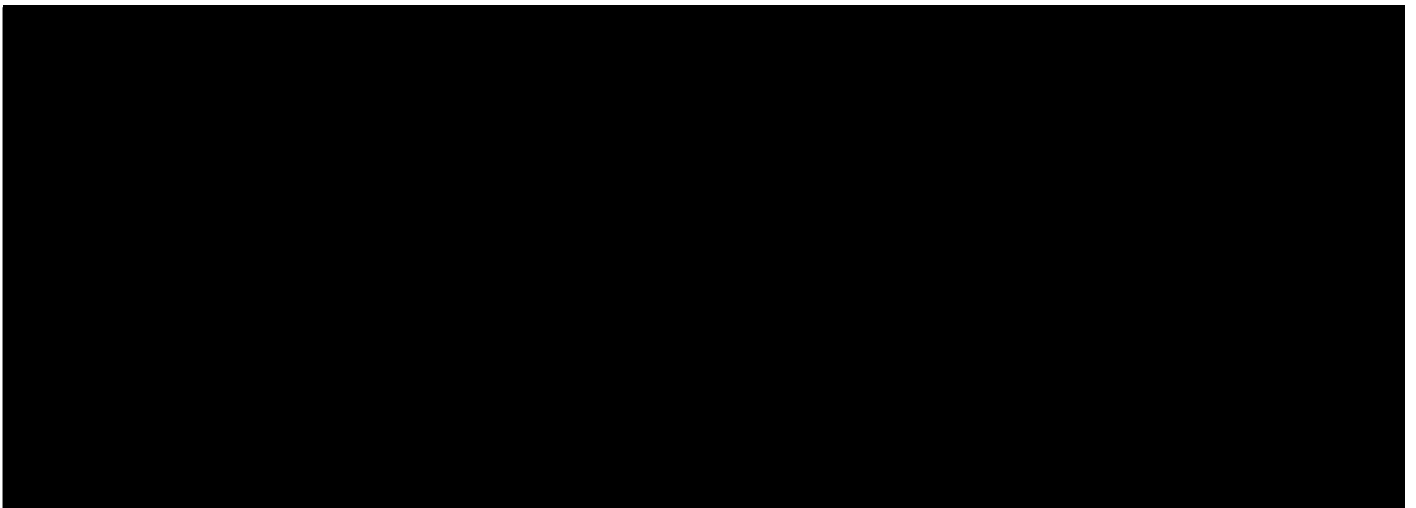
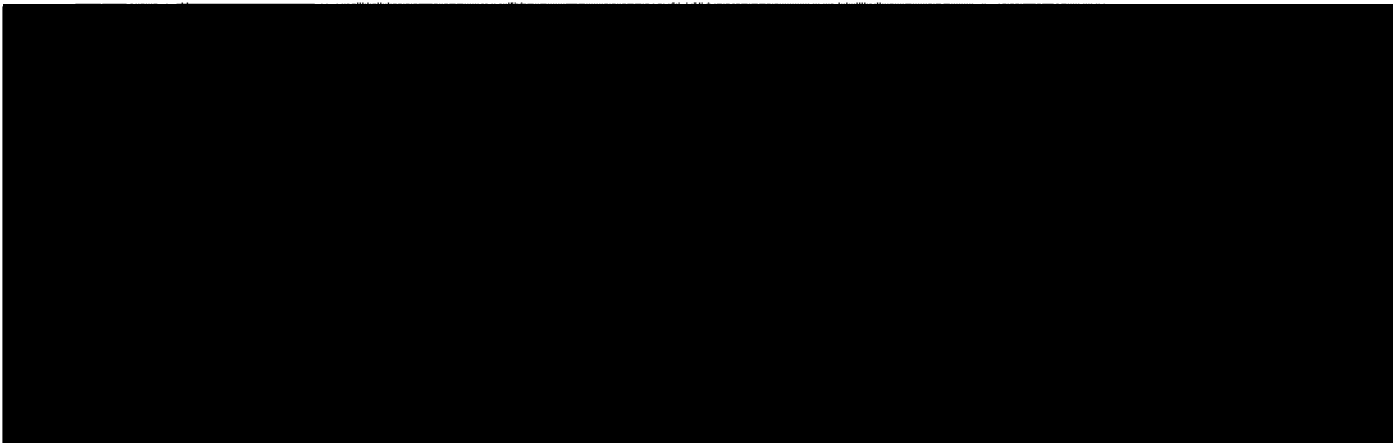
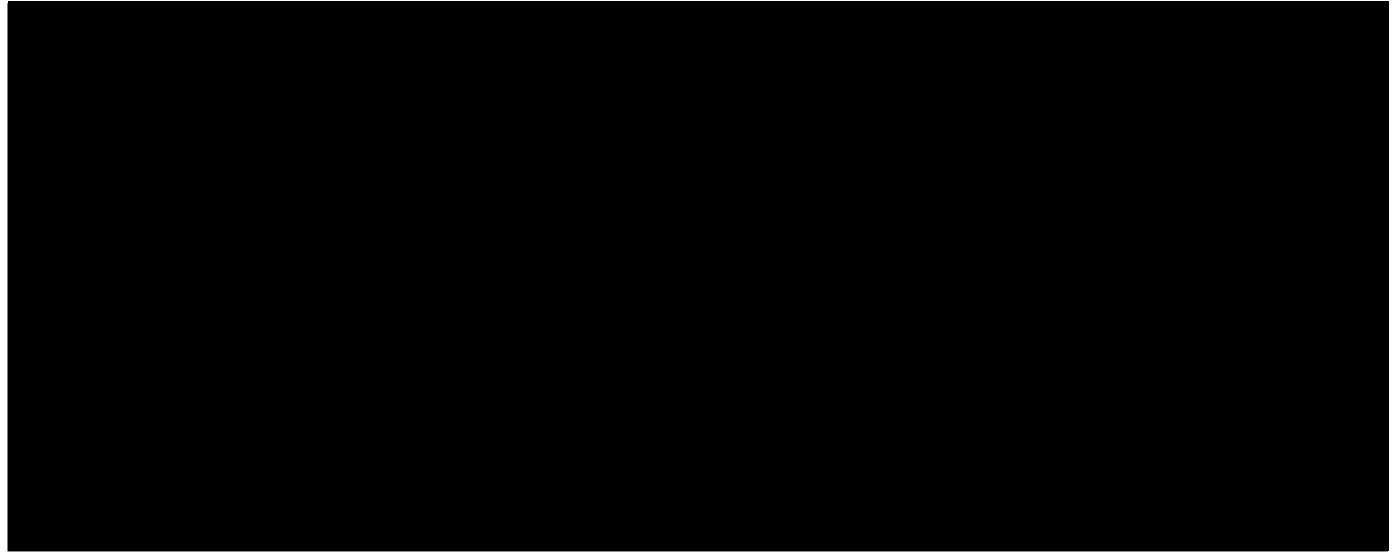
The registrant provided the following information (MRID 486308-02).

1. Determination of the active ingredient:



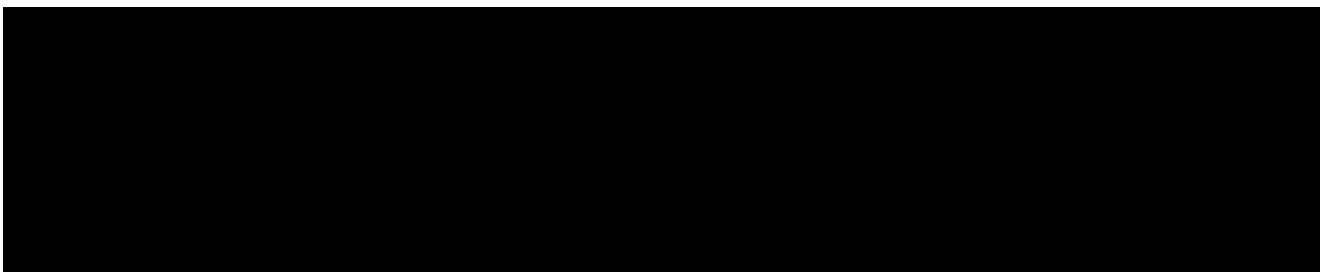
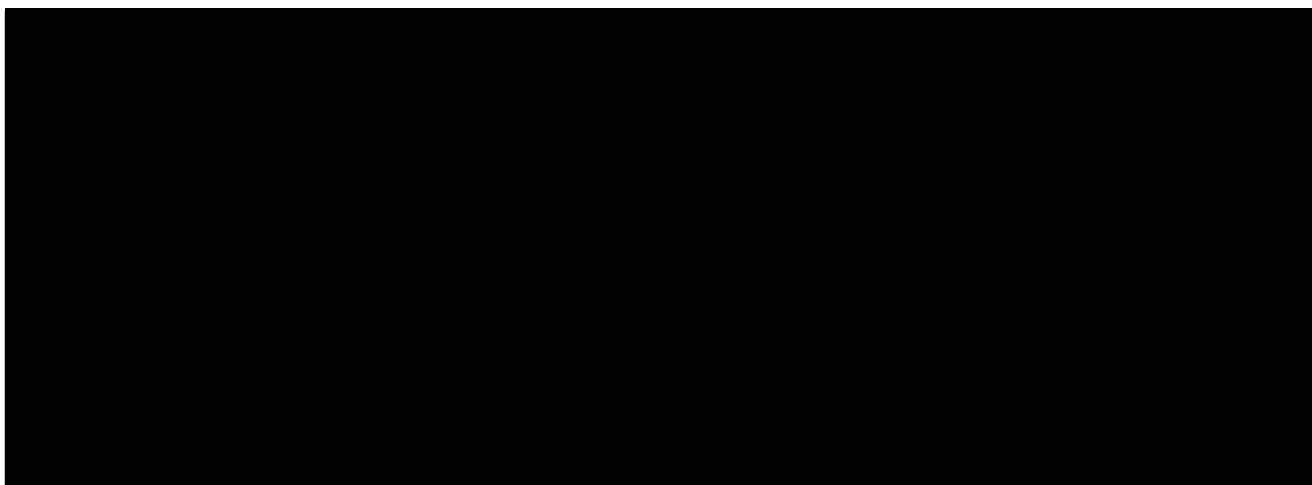
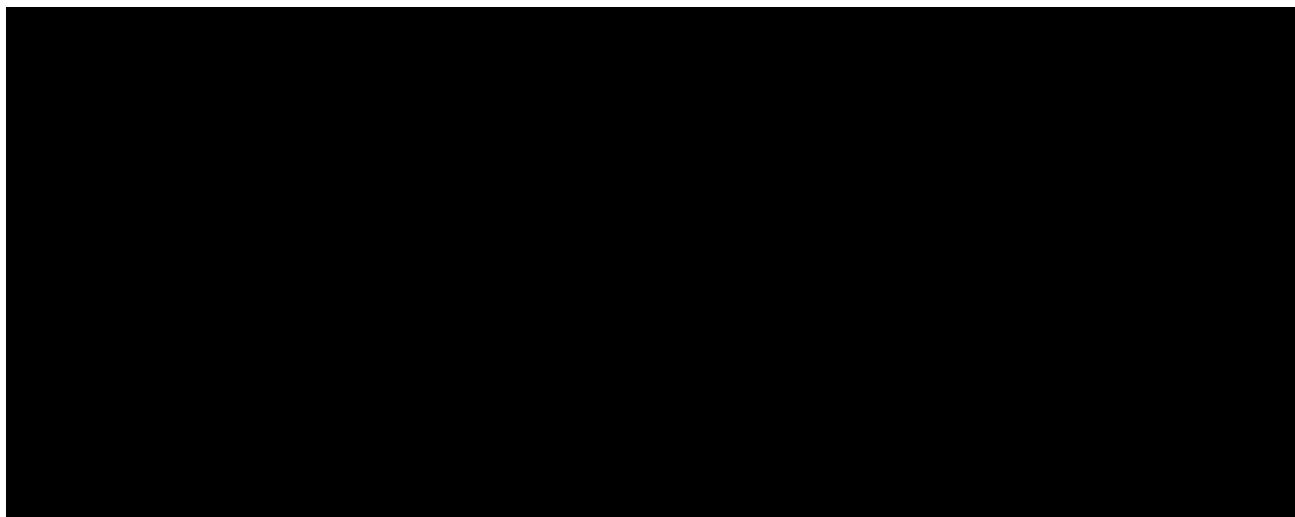
Manufacturing process information may be entitled to confidential treatment

BARCODE: 396077; FILE SYMBOL No.: 88781-R; PRODUCT: Willowood Mepiquat Chloride Technical



Manufacturing process information may be entitled to confidential treatment

BARCODE: 396077; FILE SYMBOL No.: 88781-R; PRODUCT: Willowood Mepiquat Chloride Technical

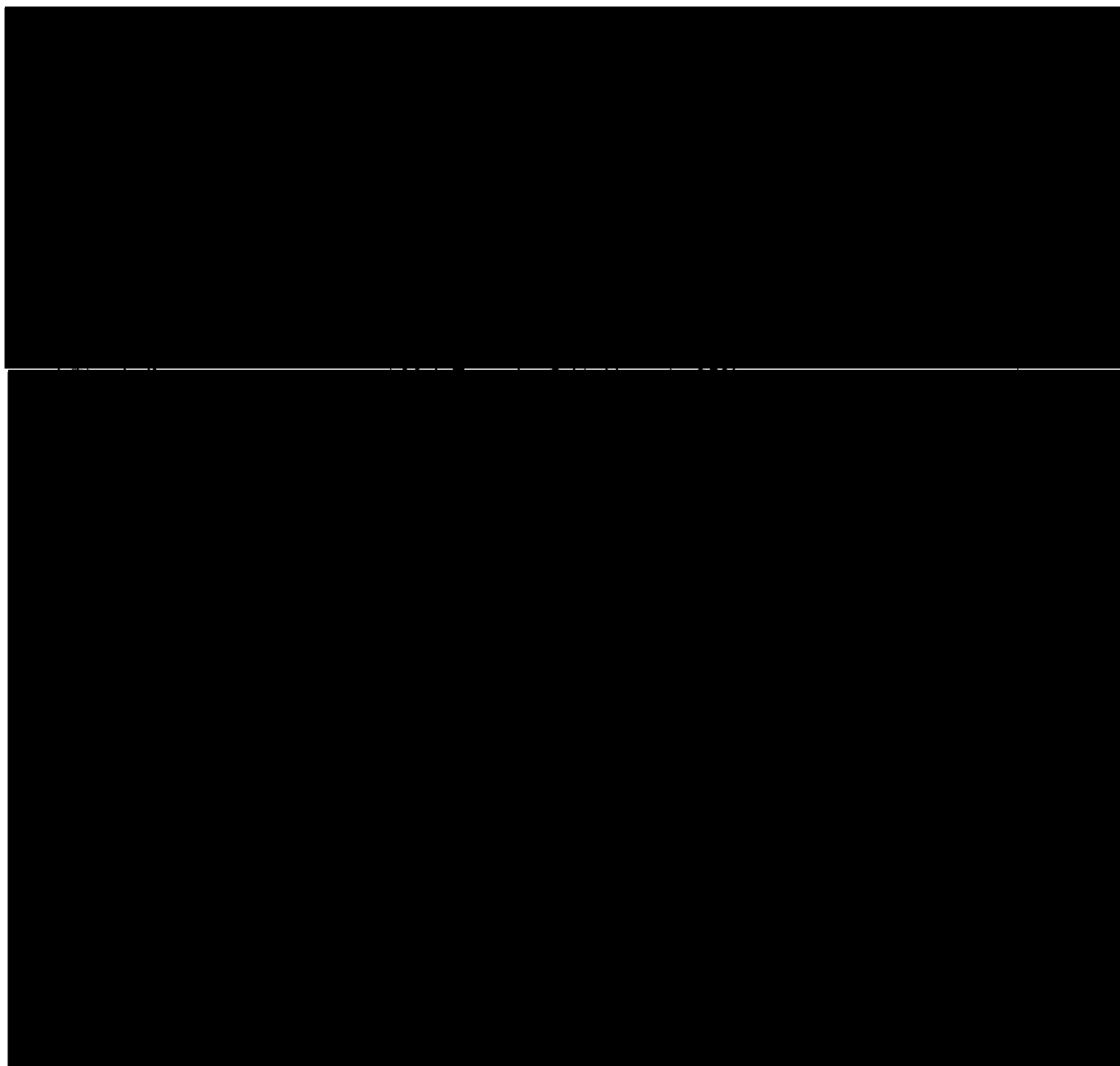


BARCODE: 396077; FILE SYMBOL No.: 88781-R; PRODUCT: Willowood Mepiquat Chloride Technical

Confidential appendix

830.1600 (description of materials used to produce the product)

The registrant provided the information below for this guideline (MRID 486308-01). MSDSs of all the starting materials and their suppliers and specifications were provided in the study (MRID 486308-01).

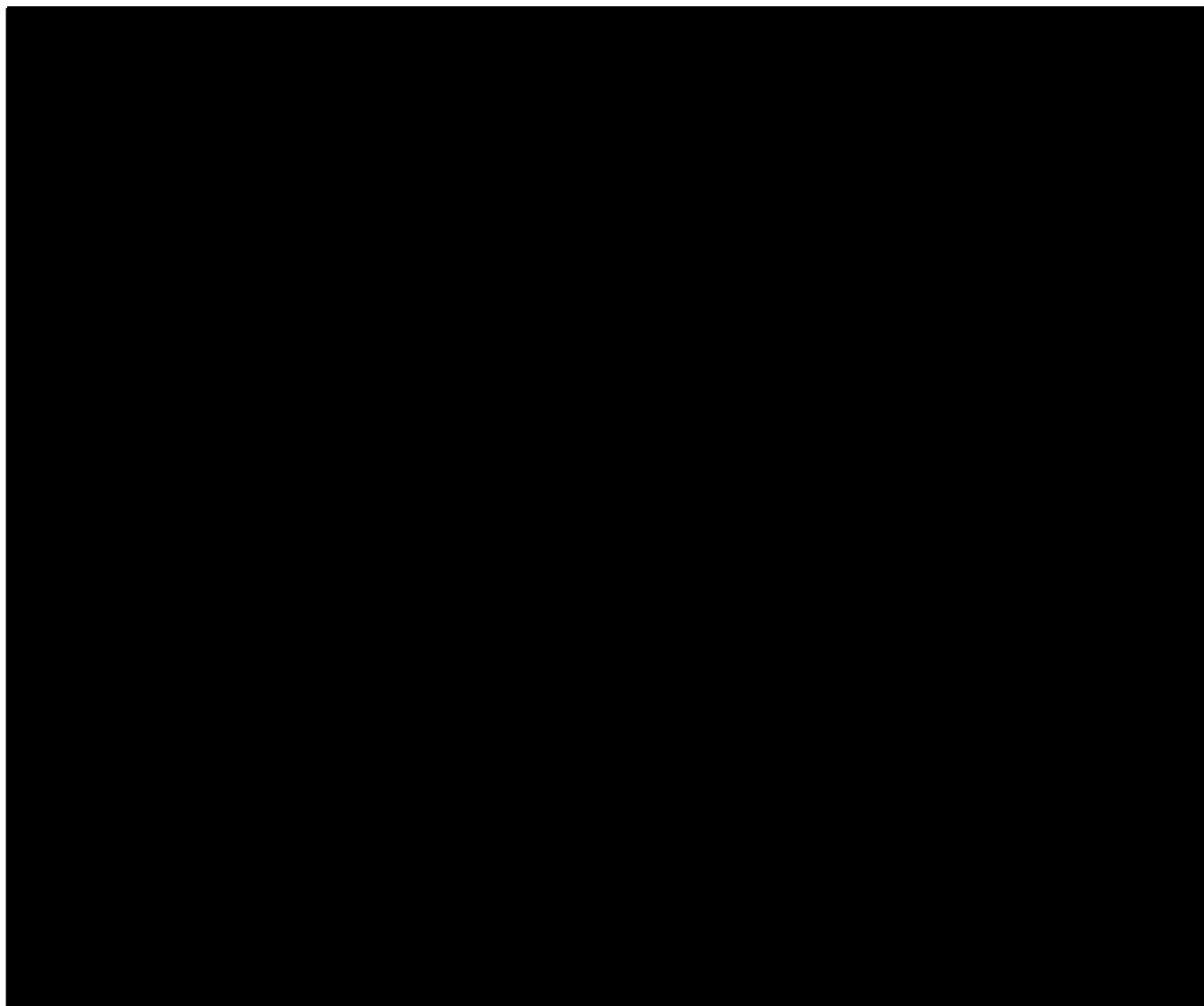


Manufacturing process information may be entitled to confidential treatment

BARCODE: 396077; FILE SYMBOL No.: 88781-R; PRODUCT: Willowood Mepiquat Chloride Technical

830.1620 (description of production process)

The registrant provided the following information for this guideline (MRID 486308-01). No quantity information was provided for the starting materials used and the product produced.



Completion of 21-Day Content Screen


PM- 20

EPA Reg. # (File Symbol) 88781-R

Decision # D

Data package delivered to
you on 10/31/11.
(date)

Jacket/Mini-jacket will be
transferred to you today.
(Pick up from Document Center)

Thank you, 

Registration Division's 21-Day Content Team

Memorandum

Date: 10 / 28 / 11

To: PM 20, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission
☐ partially accepted submission
☐ rejected submission



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 27, 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

WAGNER REGULATORY ASSOCIATES, INC
WILLOWOOD MEPIQUAT CHLORIDE, LLC
PO.BOX : 640
HOCKESSIN, DE 19707

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 18-OCT-11. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Section 3

S: 905361

Regulation: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 98781 WILLOWOOD MEPIQUAT CHLORIDE, LLC

V

Risk Manager: Registration Division, Risk Management Team 20

Product #: 98781-R Product Name: WILLOWOOD MEPIQUAT CHLORIDE TECHNIC

Override#:

Me Too

Me Too

Section3: 42750-73

Product Name: TECHNICAL MEPIQUAT CHLORIDE

Application Date: 17-Oct-2011

ic

OPP Rec'd Date: 18-Oct-2011

ic

Front End Date: 18-Oct-2011

ic

Risk Manager Send Date:

ic

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

New registration

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Study

CSF

View/Edit

New Ingredient

Request Date:

New Ingredient

Received Date:

WRA

October 17, 2011

Document Processing Desk (REGFEE)
 ATTN: Tony Kish, PM 22
 Registration Division
 U.S. Environmental Protection Agency
 Office of Pesticide Programs (7504P)
 Room S-4900, One Potomac Yard
 2777 South Crystal Drive
 Arlington, Virginia 22202-4501

Wagner Regulatory Associates, Inc.
 P.O. Box 640
 7217 Lancaster Pike, Suite A
 Hockessin, Delaware 19707

Dear Mr. Kish,

Subject: Application to register a new technical grade product containing a currently registered active ingredient - "Willowood Mepiquat Chloride Technical"

Wagner Regulatory Associates, Inc., as agent for Willowood Mepiquat Chloride, LLC (company number unassigned), is requesting registration of the above referenced product. This product is substantially similar to the mepiquat chloride product (Technical Mepiquat Chloride) registered by Albaugh Inc. under EPA Registration Number 42750-73.

In support of this request, the following documents and studies are attached:

- Letter from Willowood Mepiquat Chloride, LLC appointing Wagner Regulatory Associates, Inc. as its agent
- Application for Pesticide Registration (8570-1)
- Confidential Statement of Formula (8570-4), 2 copies
- Certification with Respect to Citation of Data (8570-34)
- Data Matrix (8570-35)
- Data Transmittal Document
- Product Identity and Composition data (3 copies) as outlined in the transmittal document
- Preliminary Analysis data (3 copies) as outlined in the transmittal document
- Physical and Chemical Properties data (3 copies) as outlined in the transmittal document
- Draft labeling, 3 copies and CD
- Certification with Respect to Label Integrity
- A copy of the EPA approved label for EPA Reg. No. 42750-73
- A copy of the receipt confirming payment of the required registration fees.
- A copy of the Request for Company Number dated August 24, 2011.
- A copy of an email regarding previous small business fee waivers.

Willowood Mepiquat Chloride, LLC has submitted registration fees to U.S.EPA in accordance with PRJA II Fee Table - FY11/FY12, for action category R310 - \$4,807. A small business fee waiver of 50% has been granted for Willowood, LLC in previous submissions for 2011. A copy of a previous approval for a 50% fee waiver is attached. A request for a company number was submitted to the Agency on August 24, 2011. To date a response has not yet been received. A copy of the request is attached.

If you have any questions about this submission please contact the undersigned at catherine@wagnerreg.com or (302) 635-7283.

Respectfully submitted,



Catherine M. Byrd
 Agent for Willowood Mepiquat Chloride, LLC

Enclosures

DATA TRANSMITTAL DOCUMENT

1. Name and Address of Submitter

Willowood Mepiquat Chloride, LLC
c/o Wagner Regulatory Associates
PO Box 640
Hockessin, DE 19707

2. Regulatory Action In Support Of Which This Package Is Submitted

Application for Registration
Willowood Mepiquat Chloride Technical

3. Transmittal Date

October 17, 2011

4. List of Submitted Studies

48630801

Vol. 1: Wagner Regulatory Associates, Inc. (2011) Willowood Mepiquat Chloride Technical-Product Identity and Composition, Description of Beginning Materials, Manufacturing Process, and Discussion of Formation of Impurities. Willowood Mepiquat Chloride, LLC, Roseburg, OR. Non-confidential portion 6 pages, Confidential portion 40 pages.

48630802

Vol. 2: Skopec, Jana (2011) Preliminary Analyses of Five Representative Production Batches of Mepiquat Chloride Technical Grade Active Ingredient (TGA1) to Determine Percent Mepiquat Chloride and to Quantify its Associated Impurities. AgriFor Scientific Pty Ltd., North Ryde, Australia. Report Number WW-035. Non-confidential portion 5 pages, Confidential portion 93 pages.

48630803

Vol. 3: Miller, Ron (2011) Willowood Mepiquat Chloride Technical – Product Chemistry Series B. Analytical and Regulatory Chemistry, Inc., Sumter, SC. Report Number ARC-EX-1000-013-P-I. 51 pages.

Company Official: Catherine M. Byrd
Name



Signature

Company Name: Wagner Regulatory Associates, Inc.
Agent for Willowood Mepiquat Chloride, LLC

Company Contact: Catherine M. Byrd
Name

(302) 635-7283
Phone

21-Day Screen Completed by
Contractor

21-Day Expires on 11-8-11

Jacket # 88781-R

MRID# 486308

Content Screen: Recommend to Pass/Fail

86-5 Review: Pass/Fail/NA

Overall Status: Recommend to Pass/Fail

Transfer This Jacket to:

Stephen Schable

PM 20

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 10-18-11

Experts In-Processing Signature: B. R.

Date 10-19-11

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>88781-R</u>		EPA Receipt Date: <u>10-18-11</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			X		
	a) All inerts (link to http://www.epa.gov/oppr001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
		X				
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)	X				
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)			X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)			X
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			X
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

A.I. added.

- * CSF approved
- * Data Package approved
- * Tackler approved

WRID:486308

IK S-4813

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses even if a product is currently registered by consulting the inert Web

site [link to <http://www.epa.gov/oppr001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/oppr001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

R 310

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGA).
Must submit Group A and B product chemistry data for each proposed product unless it's a 100% identical (repack): YES or (NO) (circle one)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGA	
		Yes	No	Yes	No	Yes	No
830.1550	Product Identity & Composition					✓	
830.1600	Description of materials used to produce the product					✓	
830.1650	Description of formulation process					✓	
830.1670	Discussion on the formation of impurities					✓	
830.1700	Preliminary analysis					✓	
830.1750	Certified limits (158.345)						
830.1800	Enforcement analytical method					✓	

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGA	
		Yes	No	Yes	No	Yes	No
830.6302	Color					✓	
830.6303	Physical State					✓	
830.6304	Odor					✓	
830.6313	Stability to normal and elevated temperatures metal and metal ions					✓	
830.6314	Oxidation/Reduction (Chemical incompatibility)					✓	
830.6315	Flammability						X
830.6316	Explosibility						X
830.6317	Storage stability						X
830.6319	Miscibility						X
830.6320	Corrosion Characteristics						X
830.6321	Dielectric Breakdown Voltage						✓
830.7000	pH					✓	
830.7050	UV/ Visible Absorption					✓	
830.7100	Viscosity						X
830.7200	Melting Point					✓	
830.7220	Boiling Point						X
830.7300	Density					✓	
830.7370	Dissociation Constant						X
830.7550	Partition Coefficient					✓	
830.7840	Water Solubility					✓	
830.7950	Vapor Pressure						X

Grayed out = data not required

R 310

New products must either: 1) supply the product specific acute toxicity 6 pack data (listed below), or 2) provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Data submitted		Cited	
		Yes	No	Yes	No
870.1100	Acute Oral (LD50)			✓	
870.1200	Acute Dermal (LD50)			✓	
870.1300	Acute Inhalation (LC50)			✓	
870.2400	Acute Eye Irritation			✓	
870.2500	Acute Dermal Irritation			✓	
870.2600	Dermal Sensitization			✓	

Efficacy – which guideline is used depends on the proposed label use

Guideline No.	Study Title	Data submitted		Cited		Comments
		Yes	No	Yes	No	
810.3100	Soil Treatments for Imported Fire Ants					
810.3200	Livestock, Poultry, Fur and Wool-Bearing Animal Treatments					
810.3300	Treatments to Control Pests of Humans and Pets					
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments					
810.3500	Premises Treatments					
810.3600	Structural Treatments					
810.3800	Methods for Efficacy Testing of Termite Baits					



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 19, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-456565
EPA File Symbol or Registration Number: 88781-R
Product Name: WILLOWOOD MEPIQUAT CHLORIDE TECHNICAL
EPA Receipt Date: 18-Oct-2011
EPA Company Number: 88781
Company Name: WILLOWOOD MEPIQUAT CHLORIDE, LLC

CATHERINE BYRD
WAGNER REGULATORY ASSOCIATES, INC
WILLOWOOD MEPIQUAT CHLORIDE, LLC
PO Box 640
HOCKESSIN, DE 19707-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R310

NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT
CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee
Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to be "m. J. [unclear]", is written over the word "Sincerely,".

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{905361Ê~

This package includes the following

☒ New Registration

☐ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr. 20

Receipt No.

S-

905361

EPA File Symbol/Reg. No.

88781-R

Pin-Punch Date:

10/18/2011

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

R310

Granted:

R310

Amount Due: \$ 4807.00

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: 

Date: 10/19/11

Remarks:

Receipt for Section 3

S: 905381

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 88781 WILLOWOOD MEPIQUAT CHLORIDE, LLC

V

Risk Manager: Registration Division, Risk Management Team 20

Product #: 88781-R Product Name: WILLOWOOD MEPIQUAT CHLORIDE TECHNICAL

Overrides:

Me Top
Section 3: 42750-73

Me Top
Product Name: TECHNICAL MEPIQUAT CHLORIDE

Application Date: 17-Oct-2011

OPP Rec'd Date: 18-Oct-2011

Front End Date: 18-Oct-2011

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

New registration

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Study

CSF

View/Edit

New Ingredient

Request Date:

New Ingredient

Received Date:

Online Payment

Step 3: Confirm Payment

1 | 2 | 3

Thank you.

Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: FRIA Service Fees

Pay.gov Tracking ID: 25410081

Agency Tracking ID: 74246551810

Transaction Date and Time: 10/17/2011 10:23 EDT

Payment Summary

Address Information	Account Information	Payment Information
Account Holder Name: Brian Heinze	Card Type: MasterCard	Payment Amount: \$4,807.00
Billing Address: 1600 HW Garden Valley Blvd	Card Number: *****6005	Transaction Date and Time: 10/17/2011 10:23 EDT
Billing Address 2: Ste 120	Decision Number:	
City: Roseburg	Registration Number:	
State / Province: OR	Company Name: Willowood Mapiquat LLC	
Zip / Postal Code: 97471	Company Number: unassigned	
Country: USA	Action Code: R310	

10/17/2011 10:23 AM

84



United States
Environmental Protection Agency
Washington, DC 20460

X

Registration

OPP Identifier Number

Amendment

Other

Application for Pesticide - Section I

1. Company/Product Number Unassigned 88781-R	2. EPA Product Manager Tony Kish	3. Proposed Classification
4. Company/Product (Name) Willowood Mepiquat Chloride, LLC/ Willowood Mepiquat Chloride Technical	PM# 22	<input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
5. Name and Address of Applicant (Include Zip Code) Willowood Mepiquat Chloride, LLC c/o Wagner Regulatory Associates, Inc. P.O. Box 640 Hockessin, DE 19707 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. 42750-73 Product Name: Technical Mepiquat Chloride	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
	If "Yes" No. per Unit Packaging wgt. container	If "Yes" No. per Package wgt. container		<input checked="" type="checkbox"/> Plastic	
* Certification must be submitted				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) HDPE lined bags	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 500 kg (1102 lbs)		5. Location of Label Directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Catherine M. Byrd		Title Agent for Willowood Mepiquat Chloride, LLC		Telephone No. (Include Area Code) (302) 635-7283	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature Catherine M. Byrd		3. Title Agent for Willowood Mepiquat Chloride, LLC			
4. Typed Name Catherine M. Byrd		10/17/2011			

DATA TRANSMITTAL DOCUMENT

1. **Name and Address of Submitter**

Willowood Mepiquat Chloride, LLC
c/o Wagner Regulatory Associates
PO Box 640
Hockessin, DE 19707

2. **Regulatory Action In Support Of Which This Package Is Submitted**

Application for Registration
Willowood Mepiquat Chloride Technical

3. **Transmittal Date**

October 17, 2011

4. **List of Submitted Studies**

Vol. 1: Wagner Regulatory Associates, Inc. (2011) Willowood Mepiquat Chloride Technical-Product Identity and Composition, Description of Beginning Materials, Manufacturing Process, and Discussion of Formation of Impurities. Willowood Mepiquat Chloride, LLC, Roseburg, OR. Non-confidential portion 6 pages, Confidential portion 40 pages.

Vol. 2: Skopec, Jana (2011) Preliminary Analyses of Five Representative Production Batches of Mepiquat Chloride Technical Grade Active Ingredient (TGA1) to Determine Percent Mepiquat Chloride and to Quantify its Associated Impurities. AgriFor Scientific Pty Ltd., North Ryde, Australia. Report Number WW-035. Non-confidential portion 5 pages, Confidential portion 93 pages.

Vol. 3: Miller, Ron (2011) Willowood Mepiquat Chloride Technical – Product Chemistry Series B. Analytical and Regulatory Chemistry, Inc., Sumter, SC. Report Number ARC-EX-1000-013-P-1. 51 pages.

Company Official: Catherine M. Byrd
Name



Signature

Company Name: Wagner Regulatory Associates, Inc.
Agent for Willowood Mepiquat Chloride, LLC

Company Contact: Catherine M. Byrd
Name

(302) 635-7283

Phone



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number
 Willowood Mepiquat Chloride, LLC, P.O. Box 640, Hockessin, DE 19707

EPA Registration Number/File Symbol
 Unassigned

Active Ingredient(s) and/or representative test compound(s)
 Mepiquat chloride

Date
 10/17/2011

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)
 Terrestrial Food and Terrestrial Non-food

Product Name
 Willowood Mepiquat Chloride Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Catherine M. Byrd

Date

10/17/2011

Typed or Printed Name and Title

Catherine M. Byrd, Agent



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

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DATA MATRIX

Date: 10/17/2011	EPA Reg No./ File Symbol: Unassigned-	Page 1 of 3
Applicant's/Registrant's Name and Address: Willowood Mepiquat Chloride, LLC c/o Wagner Regulatory Associates Inc. P.O. Box 640 Hockessin, DE 19707	Product: Willowood Mepiquat Chloride Technical	
Ingredient: Mepiquat Chloride		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT SPECIFIC					
830.1550, 830.1600, 830.1620, 830.1650, 830.1670,	Product identity & Composition/Description of Materials Used to Produce the Product/Description of Production & Formulation Process/Discussion of Formation of Impurities	✓	Willowood Mepiquat Chloride, LLC	Own	
830.1700	Preliminary Analysis		Willowood Mepiquat Chloride, LLC	Own	
830.1750	Certification of Limits		Willowood Mepiquat Chloride, LLC	Own	1
830.1800	Enforcement Analytical Method		Willowood Mepiquat Chloride, LLC	Own	
830.6302	Color		Willowood Mepiquat Chloride, LLC	Own	
830.6303	Physical State		Willowood Mepiquat Chloride, LLC	Own	
830.6304	Odor		Willowood Mepiquat Chloride, LLC	Own	
830.6313	Stability to Normal & Elevated Temperatures		Willowood Mepiquat Chloride, LLC	Own	
830.6314	Oxidation/Reduction		Willowood Mepiquat Chloride, LLC	Own	
830.6315	Flammability		Willowood Mepiquat Chloride, LLC	Own	
830.6316	Explosibility		Willowood Mepiquat Chloride, LLC	Own	
830.6317	Accelerated Storage Stability		Willowood Mepiquat Chloride, LLC	Own	
830.6319	Miscibility		Willowood Mepiquat Chloride, LLC	Own	
830.6320	Corrosion Characteristics		Willowood Mepiquat Chloride, LLC	Own	
830.6321	Dielectric Breakdown Voltage		Willowood Mepiquat Chloride, LLC	Own	
830.7000	pH		Willowood Mepiquat Chloride, LLC	Own	
830.7050	UV/Visible Light Absorption		Willowood Mepiquat Chloride, LLC	Own	
830.7100	Viscosity		Willowood Mepiquat Chloride, LLC	Own	
830.7200	Melting Point		Willowood Mepiquat Chloride, LLC	Own	
830.7220	Boiling Point		Willowood Mepiquat Chloride, LLC	Own	

Signature 	Name and Title Catherine M. Byrd, Agent for Willowood Mepiquat Chloride, LLC	Date 10/17/2011
---------------	--	--------------------



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

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DATA MATRIX

Date: 10/17/2011	EPA Reg No./ File Symbol: Unassigned-	Page 2 of 3
Applicant's/Registrant's Name and Address: Willowood Mepiquat Chloride, LLC c/o Wagner Regulatory Associates Inc. P.O. Box 640 Hockessin, DE 19707	Product: Willowood Mepiquat Chloride Technical	
Ingredient: Mepiquat Chloride		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7300	Relative Density		Willowood Mepiquat Chloride, LLC	Own	
830.7370	Dissociation Constants in Water		Willowood Mepiquat Chloride, LLC	Own	
830.7520	Particle Size, Fiber Length, and Diameter Distribution		Willowood Mepiquat Chloride, LLC	Own	
830.7550, 7560, 7570	Octanol/Water Partition Coefficient		Willowood Mepiquat Chloride, LLC	Own	
830.7840, 7860	Water Solubility		Willowood Mepiquat Chloride, LLC	Own	
830.7950	Vapor Pressure		Willowood Mepiquat Chloride, LLC	Own	
870.1100, 870.1200, 870.1300, 870.2400, 870.2500, 870.2600 Generic Data	Acute Oral Toxicity, Acute Dermal Toxicity, Acute Inhalation Toxicity, Primary Eye Irritation, Primary Dermal Irritation, Skin Sensitization Generic Data	Cite All	Bayer CropScience LP Research Triangle Park, NC Aceto Agricultural Chemicals Corp. Lake Success, NY BASF Corporation Research Triangle Park, NC Loveland Products, Inc. Greeley, CO Albaugh Inc., Ankeny, IA Nufarm USA, Inc. Research Triangle Park, NC Arysta LifeScience North America, LLC, Cary, NC Spray Drift Task Force Washington, DC	Pay	

Signature

Name and Title

Catherine M. Byrd,
Agent for Willowood Mepiquat Chloride, LLC

Date

10/17/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

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DATA MATRIX

Date: 10/17/2011	EPA Reg No./ File Symbol: Unassigned-	Page 3 of 3
Applicant's/Registrant's Name and Address: Willowood Mepiquat Chloride, LLC c/o Wagner Regulatory Associates Inc. P.O. Box 640 Hockessin, DE 19707	Product: Willowood Mepiquat Chloride Technical	
Ingredient: Mepiquat Chloride		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Gowan Pacific Group, LLC Yuma, AZ		
			Outdoor Residential Exposure Task Force, Washington, DC		
			Agricultural Reentry Task Force Washington, DC		
			Integrated Farming, Inc., Raleigh, NC		
			FIFRA Endangered Species Task Force Washington, DC		
			The Hide Group, Inc. Sardis, MS		
			Agricultural Handlers Exposure Task Force, Macon, MO		
			Gro-Pro, LLC Gig Harbor, WA		
			U.S.A. Ag Chemicals, Inc. Washington, DC		
			Tacoma Ag, LLC Brookfield, CT		
			Agsaver, LLC Washington, DC		

Signature 	Name and Title Catherine M. Byrd, Agent for Willowood Mepiquat Chloride, LLC	Date 10/17/2011
---------------	--	--------------------



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 10/17/2011	EPA Reg No./ File Symbol: Unassigned-	Page 4 of 3
Applicant's/Registrant's Name and Address: Willowood Mepiquat Chloride, LLC c/o Wagner Regulatory Associates Inc. P.O. Box 640 Hockessin, DE 19707	Product: Willowood Mepiquat Chloride Technical	
Ingredient: Mepiquat Chloride		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Generic Endangered Species Task Force, Gig Harbor, WA		

Footnotes: 1) Certification of Limits is provided in the Confidential Statement of Formula EPA form 8574-4

Signature 	Name and Title Catherine M. Byrd, Agent for Willowood Mepiquat Chloride, LLC	Date 10/17/2011
---	--	--------------------

October 17, 2011

Document Processing Desk (REGFEE)
ATTN: Tony Kish, PM 22
Registration Division
U.S. Environmental Protection Agency
Office of Pesticide Programs (7504P)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

Wagner Regulatory Associates, Inc.
P.O. Box 640
7217 Lancaster Pike, Suite A
Hockessin, Delaware 19707

Dear Mr. Kish,

Subject: Application to register a new technical grade product containing a currently registered active ingredient - "Willowood Mepiquat Chloride Technical"

Wagner Regulatory Associates, Inc., as agent for Willowood Mepiquat Chloride, LLC (company number unassigned), is requesting registration of the above referenced product. This product is substantially similar to the mepiquat chloride product (Technical Mepiquat Chloride) registered by Albaugh Inc. under EPA Registration Number 42750-73.

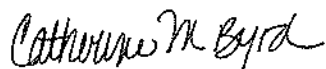
In support of this request, the following documents and studies are attached:

- Letter from Willowood Mepiquat Chloride, LLC appointing Wagner Regulatory Associates, Inc. as its agent
- Application for Pesticide Registration (8570-1)
- Confidential Statement of Formula (8570-4), 2 copies
- Certification with Respect to Citation of Data (8570-34)
- Data Matrix (8570-35)
- Data Transmittal Document
- Product Identity and Composition data (3 copies) as outlined in the transmittal document
- Preliminary Analysis data (3 copies) as outlined in the transmittal document
- Physical and Chemical Properties data (3 copies) as outlined in the transmittal document
- Draft labeling, 3 copies and CD
- Certification with Respect to Label Integrity
- A copy of the EPA approved label for EPA Reg. No. 42750-73
- A copy of the receipt confirming payment of the required registration fees.
- A copy of the Request for Company Number dated August 24, 2011.
- A copy of an email regarding previous small business fee waivers.

Willowood Mepiquat Chloride, LLC has submitted registration fees to U.S.EPA in accordance with PRIA II Fee Table - FY11/FY12, for action category R310 - \$4,807. A small business fee waiver of 50% has been granted for Willowood, LLC in previous submissions for 2011. A copy of a previous approval for a 50% fee waiver is attached. A request for a company number was submitted to the Agency on August 24, 2011. To date a response has not yet been received. A copy of the request is attached.

If you have any questions about this submission please contact the undersigned at catherine@wagnerreg.com or (302) 635-7283.

Respectfully submitted,



Catherine M. Byrd
Agent for Willowood Mepiquat Chloride, LLC

Enclosures



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OIPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 10/17/2011	EPA Reg No./ File Symbol: Unassigned-	Page 2 of 3
Applicant's/Registrant's Name and Address: Willowood Mepiquat Chloride, LLC c/o Wagner Regulatory Associates Inc. P.O. Box 640 Hockessin, DE 19707	Product: Willowood Mepiquat Chloride Technical	
Ingredient: Mepiquat Chloride		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Willowood Mepiquat Chloride, LLC	Own	
			Willowood Mepiquat Chloride, LLC	Own	
			Willowood Mepiquat Chloride, LLC	Own	
			Willowood Mepiquat Chloride, LLC	Own	
			Willowood Mepiquat Chloride, LLC	Own	
			Willowood Mepiquat Chloride, LLC	Own	
			Willowood Mepiquat Chloride, LLC	Own	
			Bayer CropScience LP	Pay	
			Research Triangle Park, NC		
			Aceto Agricultural Chemicals Corp.		
			Lake Success, NY		
			BASF Corporation		
			Research Triangle Park, NC		
			Loveland Products, Inc.		
			Greeley, CO		
			Albaugh Inc., Ankeny, IA		
			Nufarm USA, Inc.		
			Research Triangle Park, NC		
			Arysta LifeScience North America, LLC, Cary, NC		
			Spray Drift Task Force		
			Washington, DC		

Signature

Name and Title

Catherine M. Byrd
Agent for Willowood Mepiquat Chloride, LLC

Date

10/17/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street, S.W.

WASHINGTON, D.C. 20460

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DATA MATRIX

Date: 10/17/2011	EPA Reg No./ File Symbol: Unassigned-	Page 3 of 3
Applicant's/Registrant's Name and Address: Willowood Mepiquat Chloride, LLC c/o Wagner Regulatory Associates Inc. P.O. Box 640 Hockessin, DE 19707	Product: Willowood Mepiquat Chloride Technical	
Ingredient: Mepiquat Chloride		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Gowan Pacific Group, LLC Yuma, AZ		
			Outdoor Residential Exposure Task Force, Washington, DC		
			Agricultural Reentry Task Force Washington, DC		
			Integrated Farming, Inc., Raleigh, NC		
			FIFRA Endangered Species Task Force Washington, DC		
			The Hide Group, Inc. Sardis, MS		
			Agricultural Handlers Exposure Task Force, Macon, MO		
			Gro-Pro, LLC Gig Harbor, WA		
			U.S.A. Ag Chemicals, Inc. Washington, DC		
			Tacoma Ag, LLC Brookfield, CT		
			Agsaver, LLC Washington, DC		
			Generic Endangered Species Task Force, Gig Harbor, WA		

Signature

Catherine M. Byrd

Name and Title

Catherine M. Byrd
Agent for Willowood Mepiquat Chloride, LLC

Date

10/17/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

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DATA MATRIX

Date: 10/17/2011	EPA Reg No./ File Symbol: Unassigned-	Page 4 of 3
Applicant's/Registrant's Name and Address:	Willowood Mepiquat Chloride, LLC c/o Wagner Regulatory Associates Inc. P.O. Box 640 Hockessin, DE 19707	Product: Willowood Mepiquat Chloride Technical
Ingredient: Mepiquat Chloride		

Footnotes: 1) Certification of Limits is provided in the Confidential Statement of Formula EPA form 8574-4

CONFIDENTIAL

Signature 	Name and Title Catherine M. Byrd Agent for Willowood Mepiquat Chloride, LLC	Date 10/17/2011
---	---	--------------------

Willowood Mepiquat Chloride, LLC

August 24, 2011

To: Whom it May Concern

Re: Designation of Agent for:
Willowood Mepiquat Chloride, LLC
1600 NW Garden Valley Blvd.
Suite 120
Roseburg, OR 97471

Dear Sir or Madam:

This letter serves as notification that Willowood Mepiquat Chloride, LLC has appointed Wagner Regulatory Associates, Inc. (WRA, Inc.) to serve as the Agent on our company's behalf regarding all state and federal regulatory matters relative to its Mepiquat Chloride products that Willowood Mepiquat Chloride, LLC will register with US EPA and the states. Please forward all correspondence for Willowood Mepiquat Chloride, LLC and its products to:

Wagner Regulatory Associates, Inc.
P.O. Box 640
Hockessin, DE 19707-0640

Thank you for your time and assistance. Please feel free to call me at if you have any questions.

Respectfully submitted,


Brian Heinze
President/CEO

cc: WRA, Inc.

1600 NW Garden Valley Blvd., Suite 120 | Roseburg, Oregon 97471

August 24, 2011

U.S. Environmental Protection Agency
Document Processing Desk (NEWCO)
Office of Pesticide Programs
Room S4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202

WRA

Wagner Regulatory Associates, Inc.
P.O. Box 640
7217 Lancaster Pike, Suite A
Hockessin, Delaware 19707

Subject: Request for a company number and establish an official address
with EPA

To Whom It May Concern:

This letter serves as request for a company number and to establish an official
address for Willowood Mepiquat Chloride, LLC.

Company Name: Willowood Mepiquat Chloride, LLC
Company Address: 1600 NW Garden Valley Blvd, Suite 120
Roseburg, OR 97471
Company Phone Number: 541.679.9963

Agent Name: Wagner Regulatory Associates, Inc.
Contact Name: Catherine Byrd
Contact Phone Number: (302) 635-7283
Contact Email Address: catherine@wagnerreg.com
Agent Mailing Address: P.O. Box 640
Hockessin, Delaware 19707

Please forward all correspondence for Willowood Mepiquat Chloride, LLC and its
products to Wagner Regulatory Associates, Inc.

Thank you for your time and assistance. Please feel free to contact me if you
have any questions.

Respectfully submitted,



Catherine M. Byrd
Agent for Willowood Mepiquat Chloride, LLC.

Catherine Byrd

From: DCOPPAPPS01/DC/USEPA/US@epamail.epa.gov on behalf of Pesticide Registration Improvement Act [Pesticide_Registration@epamail.epa.gov]
Sent: Wednesday, September 28, 2011 6:20 PM
To: Catherine@wagnerreg.com
Subject: Waiver: Approval (50%) - No payment requested

September 28, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-454383

EPA File Symbol or Registration Number: 87290-EL Product Name: WILLOWOOD OXYTET 17WP EPA
Application Receipt Date: 07-Sep-2011 EPA Waiver Request Receipt Date: 07-Sep-2011 EPA
Company Number: 87290 Company Name: WILLOWOOD, LLC

JANELLE KAY
PYXIS REGULATORY CONSULTING, INC.
WILLOWOOD, LLC
4110 136TH ST., NW
GIG HARBOR, WA 98332-

SUBJECT: Approval of 50% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has approved your request for 50% waiver of the pesticide registration fee associated with the action referenced above. The decision review period for this action will begin on the date of this letter.

The Action has been identified as Action Code: R300

NEW PRODUCT;ME-TOO PRODUCT FAST TRACK;

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman, at (703) 308-9362.

Sincerely,

Oscar Morales, Director
Information Technology & Resources
Office of Pesticide Programs

Management Division

Willowood Mepiquat Chloride, LLC

August 24, 2011

To: Whom it May Concern

Re: Designation of Agent for;
Willowood Mepiquat Chloride, LLC
1600 NW Garden Valley Blvd.
Suite 120
Roseburg, OR 97471

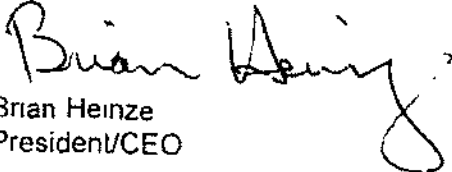
Dear Sir or Madam:

This letter serves as notification that Willowood Mepiquat Chloride, LLC has appointed Wagner Regulatory Associates, Inc. (WRA, Inc.) to serve as the Agent on our company's behalf regarding all state and federal regulatory matters relative to its Mepiquat Chloride products that Willowood Mepiquat Chloride, LLC will register with US EPA and the states. Please forward all correspondence for Willowood Mepiquat Chloride, LLC and its products to:

Wagner Regulatory Associates, Inc.
P.O. Box 640
Hockessin, DE 19707-0640

Thank you for your time and assistance. Please feel free to call me at if you have any questions.

Respectfully submitted,


Brian Heinze
President/CEO

cc: WRA, Inc.

1600 NW Garden Valley Blvd., Suite 120 | Roseburg, Oregon 97471

Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL		
EPA Registration #	Date Submitted to EPA	Electronic file name
XXXXX-R	10/17/2011	XXXXXX.XXXXXX.20110923.V1.pdf

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.



Signature

10/17/2011

Date

Catherine M. Byrd
Name (typed)

Agent for Willowood Mepiquat Chloride, LLC
Title

There is an **ELECTRONIC LABEL** for this action

You can use Acrobat to compare the e-label to the previous version (and find the changes). You can also use Acrobat to mark-up the e-label with your comments.

If e-label was submitted via

CD-ROM with paper application

then you will find e-label in

Electronic Label Library

If the e-label is not found in the ELL then it was probably not named correctly and could not be entered into the ELL. However, the file can be retrieved from the CD which is retained by the Front End.

or

If e-label was submitted via

XML E-Submission (no paper)

then you will find e-label in

Documentum

See overview of processing e-labels on other side of this sheet.

If you have any questions on e-labels, please contact one of your division e-label experts:

AD	Willie Abney	308-1689
	Rena Whitaker	308-7003
	Tracy Lantz	308-6415
BPPD		
RD	Tom Harris	308-9423

42750-73

5/18/2011

10f6



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

Morris Gaskins
Albaugh Inc.
P.O. Box 2127
Valdosta, GA 31604

MAY 18 2011

Subject: Application for Pesticide Notification (PRN 2007-4)
Submission date: 4/12/11
Product Name: Technical Mepiquat Chloride
EPA Reg. No.: 42750-73
EPA Decision Number: 448492

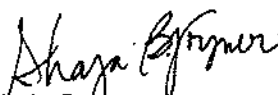
Dear Mr. Gaskins,

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 2007-4. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 2007-4 and finds that the action(s) requested fall within the scope of PRN 2007-4.

The Agency acknowledges the revised language for Container Disposal in the *Storage and Disposal* Section on page 2 of 3.

The label submitted with the application has been stamped "Notification" and will be placed in our records. If you have questions concerning this letter, please contact Erin Malone at 703-347-0253 or me at 703-308-3194.

Sincerely,


Shaja Joyner
Product Manager 20
Fungicide Branch
Registration Division (7504P)



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 42750-73	2. EPA Product Manager S. Joyner	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Technical Mepiquat Chloride	PM# 20	
5. Name and Address of Applicant (Include ZIP Code) Albaugh Inc. P.O. Box 2127 Valdosta, GA 31604-2127 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Label notification to revise Container Disposal instructions under PR Notice 2007-4 as amended April, 2008. (Replace original notification 42750-73)
This notification is consistent with the provisions of PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR 156.10, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with 40 CFR 156.10, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under section 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	<input type="checkbox"/> Plastic	
		If "Yes" Package wgt.	No. per container	<input type="checkbox"/> Glass	
			4	<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 200 kg 2.5 gal, 30 gal, Bulk		5. Location of Label Directions <input checked="" type="checkbox"/>	
6. Manner in Which Label Is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)				
Name Morris Gaskins		Title Registrations Manager		
		Telephone No. (Include Area Code) 229-244-3288		
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			Date Application Received (Stamped)	
2. Signature 		3. Title Registrations Manager		
4. Typed Name Morris Gaskins		5. Date 4/12/11		

CORPORATE OFFICE
1525 NE 36th Street
Ankeny, IA 50021
515.964.9444 (Phone)
800.247.8013 (Toll Free)
515.964.7613 (FAX)

ALBAUGH, INC.

3066
GEORGIA OFFICE
P.O. Box 2127
Valdosta, GA 31604-2127
229.244.3288 (Phone)
229.244.5841 (FAX)

Fed-X

April 12, 2011

Document Processing Desk (NOTIFY)
Ms. Shaja Joyner (PM 20)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room 5-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

RE: PR Notice 2007-4

Dear Ms. Joyner,

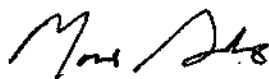
The enclosed submission for the below referenced registration is a label notification in response to the Agency's PR Notice 2007-4 for Container Disposal revision.

PRODUCT	EPA REG. NO.
Technical Mepiquat Chloride	42750-73
Myclobutanil TGA1	42750-142

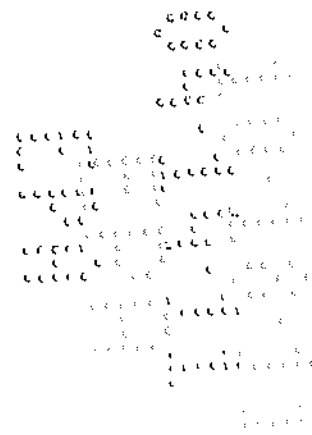
Three copies of the draft label with changes noted with strikeout/bold text are enclosed. The PRN certification statement is listed on the 8570-1 forms.

Please call if you have any questions.

Regards,



Morris Gaskins
Registrations Manager
Albaugh, Inc.



PREMIER SUPPLIER OF OFF-PATENT CROP PROTECTION PRODUCTS
www.albaughinc.com

S 89104

4066

NOTIFICATION

MAY 18 2011

TECHNICAL MEPIQUAT CHLORIDE
FOR MANUFACTURING PURPOSES ONLY

ACTIVE INGREDIENT:

Mepiquat Chloride: N,N-dimethylpiperidinium chloride..... 98.0%

OTHER INGREDIENTS:..... 2.0%

TOTAL100.0%

KEEP OUT OF REACH OF CHILDREN

WARNING

FIRST AID	
IF SWALLOWED:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
IF INHALED:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.• Call a poison control center or doctor for further treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-424-9300 for emergency medical treatment information.	

EPA Reg. No. 42750-73

EPA Est. No. xxxxxxxx

Net Weight: _____

Manufactured For:
Albaugh, Inc.
121 NE 18th Street
Ankeny, IA 50021FOR CHEMICAL SPILL, LEAK FIRE, OR EXPOSURE
CALL CHEMTREC (800) 424-9300

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING

May be fatal if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Harmful if absorbed through skin or inhaled. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Avoid breathing dust. Remove contaminated clothing and wash clothing before reuse.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only for formulation into a plant growth regulator for use on cotton. This product may be used to formulate products for any additional use(s) not listed on this label if the formulator, user group, or grower has compiled with U.S. EPA data submission requirements regarding support of such use(s).

Each formulator using this product to formulate an end use pesticide product is responsible for obtaining an EPA registration for its end use product.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original container in a cool, dry area.

Pesticide Disposal: Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Non-refillable container. DO NOT reuse or refill this container. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into formulation equipment, then offer for recycling, if available, or dispose of liner in a sanitary landfill or by incineration if allowed by State and local authorities. If burned, stay out of smoke. If drum or other outer container is contaminated and cannot be reused, dispose of in the manner required for its liner.

CONDITIONS OF SALE AND WARRANTY

The DIRECTIONS FOR USE of this product reflect the opinion of experts based on field use and tests. The directions are believed to be reliable and should be followed carefully. However, it is impossible to eliminate all risks inherently associated with use of this product. Crop injury, ineffectiveness, or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of ALBAUGH, INC. or the Seller. All such risks shall be assumed by the Buyer.

ALBAUGH, INC. warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes referred to in the Directions for Use subject to the inherent risks referred to above. ALBAUGH, INC. MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS FOR ANY PARTICULAR PURPOSE OR OF MERCHANTABILITY OR ANY OTHER EXPRESS OR IMPLIED WARRANTY. THIS WARRANTY DOES NOT EXTEND TO, AND THE BUYER SHALL BE SOLELY RESPONSIBLE FOR, ANY AND ALL LOSS OR DAMAGE WHICH RESULTS FROM THE USE OF THIS PRODUCT IN ANY MANNER WHICH IS INCONSISTENT WITH THE LABEL DIRECTIONS.

BUYER'S EXCLUSIVE REMEDY AND MANUFACTURER'S OR SELLER'S EXCLUSIVE LIABILITY FOR ANY AND ALL CLAIMS, LOSSES, DAMAGES, OR INJURIES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER OR NOT BASED IN CONTRACT, NEGLIGENCE, STRICT LIABILITY IN TORT OR OTHERWISE, SHALL BE LIMITED, AT THE MANUFACTURER'S OPTION, TO REPLACEMENT OF OR THE REPAYMENT OF THE PURCHASE PRICE FOR THE QUANTITY OF PRODUCT WITH RESPECT TO WHICH DAMAGES ARE CLAIMED. When Buyer suffers losses or damages resulting from the use or handling of this product (including claims based on contract, negligence, strict liability, or other legal theories), Buyer must promptly notify Seller in writing of any claims to be eligible to receive either remedy stated above. IN NO CASE SHALL ALBAUGH, INC. OR THE SELLER BE LIABLE FOR CONSEQUENTIAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT. ALBAUGH, INC. and the Seller offer this product, and the Buyer accepts it, subject to the foregoing Conditions of Sale and Warranty, which may be varied only by agreement in writing signed by a duly authorized representative of ALBAUGH, INC. No employee or agent of ALBAUGH, INC. or the Seller is authorized to vary or exceed the terms of this Warranty in any other manner.

DISCLAIMER AND INDEMNITY FOR FORMULATORS' USES

The manufacturer expressly disclaims all liability for claims and actions (whether based on contract, tort, strict liability, or breach of warranty) arising out of, resulting from or connected with a formulation containing this product when used for any purpose other than those uses set forth in the Directions for Use. The manufacturer has not developed scientific data to support, nor has it explicitly or implicitly approved, any uses other than those in the Directions for Use.

Any formulator or buyer who uses this product in formulations for any other than those stated in the Directions for Use above assumes all liability for claims and actions arising out of, connected with or resulting from such use and agrees by so using this product to indemnify and hold harmless the manufacturer from such claims and actions.

This Disclaimer and Indemnity is in addition to, not in lieu of, the above Conditions of Sale and Warranty.

Willowood Mepiquat Chloride Technical**Active Ingredient:**

Mepiquat Chloride: N, N-dimethylpiperidinium chloride 98.6%

Other Ingredients..... 1.4%**Total:**..... 100.0%**KEEP OUT OF REACH OF CHILDREN
WARNING****First Aid**

IF SWALLOWED	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 to 20 minutes. • Call a poison control center or doctor for treatment advice.
If INHALED	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
Have the product container or label with you when calling a poison control center, doctor, or going for treatment. For emergency information concerning this product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378 seven days a week, 6:30 am to 4:30 pm Pacific Time (NPIC Web site: www.npic.orst.edu) .	

EPA Reg. No.

EPA Est. No.

Net Contents: _____

Manufactured for:
Willowood Mepiquat Chloride LLC
1600 NW Garden Valley Blvd, Suite 120
Roseburg, OR 97471

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING**

May be fatal if swallowed. Harmful if absorbed through skin or inhaled. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Avoid breathing dust. Wash thoroughly with soap and warm water after handling and before eating, drinking, or using tobacco. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only for formulation into a plant growth regulator for use on cotton.

This product may be used to formulate products for any additional use(s) not listed on this label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding support of such use(s).

Each formulator using this product to formulate an end use pesticide product is responsible for obtaining an EPA registration for its end use product.

XXXXXX-XXXXX.20110923.V1
Mepiquat Chloride Technical Draft label
Willowood Mepiquat Chloride LLC

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage: Store in a cool dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food, and feed. Store in original container and out of the reach of children, preferably in a locked storage area.

Pesticide Disposal: Pesticide wastes are toxic. Improper disposal of excess pesticide or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Handling:

Container Handling (Bags): Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Then offer for recycling if available or reconditioning if appropriate or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Container Handling (Plastic): Nonrefillable container. Do not reuse or refill this container. Triple rinse (or equivalent). Then offer for recycling if available or reconditioning if appropriate or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

REFILLABLE CONTAINER: Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into formulation equipment. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Willowood Mepiquat Chloride LLC. To the extent consistent with applicable law, all such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, WILLOWOOD MEPIQUAT CHLORIDE LLC MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. To the extent consistent with applicable law, no agent of Willowood Mepiquat Chloride LLC is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, WILLOWOOD MEPIQUAT CHLORIDE LLC DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT WILLOWOOD MEPIQUAT CHLORIDE LLC'S ELECTION, THE REPLACEMENT OF PRODUCT.

WILLOWOOD MEPIQUAT CHLORIDE LLC
10000 WILLOWOOD DRIVE
MARIETTA, GA 30067
(770) 426-1100
WWW.WILLOWOODLLC.COM

